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OPEN-ENDED TECHNICAL EXPERT GROUP ON
IDENTIFICATION REQUIREMENTS OF LIVING
MODIFIED ORGANISMS INTENDED FOR DIRECT USE
AS FOOD OR FEED, OR FOR PROCESSING
Montreal, 16-18 March 2005
Item 3.1 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION (ARTICLE 18)

Compilation of views and relevant information on paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety**

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SUBMISSIONS FROM GOVERNMENTS

ARGENTINA [2 JULY 2004]
[SUBMISSION: SPANISH]

Cuestiones vinculadas a la aplicación del artículo 18.2.a del Protocolo de Cartagena: Comentarios de la Argentina

a) Experiencia en la implementación de la primera frase del artículo 18.2.a.

A pesar de que el 11 de septiembre de 2003 entró en vigor el Protocolo de Cartagena sobre la Seguridad de la Biotecnología, son muy pocos los casos en los que a nuestros embarques de granos commodities genéticamente modificados se les requirió la inclusión del "may contain" dentro de la factura comercial.

b) Comentarios respecto a los requisitos que están estipulados bajo este artículo, sobretodo el tema del puede contener, los umbrales de presencia adventicia y los identificadores únicos.

- "May Contain"/ "puede llegar a contener"

El párrafo 2 (a) del Artículo 18 establece requisitos de identificación para el movimiento transfronterizo intencional de OVMs destinados a uso directo como alimento humano o animal, o para procesamiento.

Respecto al "puede llegar a contener", Argentina sostiene que este debería incluirse dentro de la factura comercial que el exportador le entrega al importador al momento del envío del embarque. El importador deberá ser responsable de recibir esta información y mantenerla al momento del ingreso de ese OVM.

Este "puede llegar a contener" debería contener esta información: "Disposición del Protocolo de Cartagena sobre Seguridad de la Biotecnología: Este embarque puede llegar a contener organismos vivos modificados destinados a uso directo como alimento humano o animal, o para procesamiento, que no están destinados para su introducción intencional en el medio". Argentina considera que debe seguirse literalmente el texto del Protocolo y cumplir con los requisitos de información que en él se estipulan. Según esta opinión, esta información basta para cumplir el propósito general del Protocolo, que es el la conservación y uso sostenible de la biodiversidad.

Es importante remarcar que la fuente principal de información, e instrumento esencial para la toma de decisiones y cumplimiento de los objetivos del Protocolo respecto a los movimientos transfronterizos de OVMs, es el "Centro de Intercambio de Información". En este sentido, desde Argentina abogamos por avanzar en su fortalecimiento, acceso y desarrollo, como paso previo a la discusión de cuestiones comerciales respecto a la implementación del artículo 18.2. A su vez, sostenemos que no es necesario repetir, dentro de la factura comercial, la información disponible a través de este sitio.

El último exportador, con anterioridad al movimiento transfronterizo, y el primer importador después de dicho movimiento deberán figurar dentro de la factura comercial o en un anexo a ella, indicando sus nombres y los datos necesarios para su ubicación, pues serán los puntos de contacto en caso de necesidad de mayor información.

Argentina sostiene además que, los requisitos adicionales a los acordados en la Primera Reunión de las Partes, deberán previamente discutirse dentro del grupo de expertos sobre identificación de OVMs.

No obstante esto, desde la Argentina sostenemos que antes de discutir cualquier información adicional, primero deberían estudiarse las implicaciones de costo, sobretodo para los países en desarrollo.

Además, Argentina considera que, antes de avanzar en cuestiones comerciales, los países que han ratificado el Protocolo también deberían tener vigentes sus respectivos marcos nacionales de bioseguridad.

- Umbral

Argentina sostiene que la documentación con la frase "puede llegar a contener" se deberá utilizar para todos los movimientos transfronterizos de commodities destinados a uso directo como alimento humano o animal, o para procesamiento, en los casos en que un OVM de esa especie de commodity esté autorizado en el país exportador, o se venda desde éste, excepto:

i. Embarques para los cuales el país exportador no tiene comercio de OVM de esa especie o

ii. Cuando el exportador y el importador han definido contractualmente un embarque "libre de OVM" si tal embarque tiene un mínimo de 95% de contenido libre de OVM, y si esa definición no entra en conflicto con normativa del país importador.

c) Experiencia en el uso de los identificadores únicos dentro del marco del PBC.

A partir de Abril de 2004 la UE exige, dentro de la factura comercial, la identificación del grano OVM, a través de un sistema de identificadores únicos. Argentina esta preocupada en que se implemente un sistema de identificación única sin que se haya discutido en el marco del Protocolo de Cartagena.

AUSTRALIA

[29 JUNE 2004]
[SUBMISSION: ENGLISH]

Australia thanks the Executive Secretary for the opportunity to offer its views on issues relevant to paragraph 2(a) of Article 18 of the Cartagena Protocol on Biosafety, as set out in notification SCBD/BS/CS/WDY/jh/42384. Australia notes that the Open-Ended Technical Experts Group (Open-Ended TEG) should take into account the extensive work already undertaken on this issue, as outlined in the chapeau of the decision BS-I/6 taken at the first meeting of the Parties (MOP-1).

Australia supports the outcomes of the Technical Experts Group of March 2002 and believes this document should form the basis for further work. However, it should be noted that these comments do not represent a view that such documentation is necessary to achieve the objectives of the Protocol.

Australia notes that very few countries have implemented obligations under the Protocol, and in particular in relation to documentation requirements for LMOs-FFP. Discussion of such issues as unique identification, co-mingling of LMOs with non-LMO shipments and any possible relevance of Article 17 (Unintentional movements) is premature.

(a) Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18;

Australia is not a party to the Protocol and therefore has not implemented these requirements. However, implementation of these requirements by parties to the Protocol that also import Australian agricultural commodities mean that Australian agricultural exporters must comply with the requirements of the Protocol as transposed into the domestic law of these parties in order to gain market access.

Australia views the requirements of the first sentence to be simple, practical and not unduly burdensome or costly to implement or understand, for the importer and exporter.

(b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2(a) of Article 18, including specification of the identity of the living modified organisms (LMOs) that are intended for direct use as food or feed, or for processing (FFP) (whether the extent of information should include taxonomic name, the gene modification inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs; and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification;

Australia notes that the decision that sets out the terms of reference of the Open-Ended TEG ranked the terms of reference *by priority*, with (a), (b) and (c) being of a higher priority than (d) and (e). Australia requests that the Executive Secretariat preserve this priority ranking when preparing its synthesis of information and views, for consideration by the Open-Ended TEG.

Australia has prepared a submission that uses the terms of reference of the Open-Ended TEG, as set down in the decision taken at MOP-1, as a framework for comments.

The Open-Ended Technical Expert Group shall:

1. Examine the issues of specifying the identity of living modified organisms that are intended for direct use as food or feed, or for processing and unique identification mentioned in the second sentence of paragraph 2 (a) of Article 18 in relation to the "may contain" language of the first sentence of the same paragraph, and any other issues that may be relevant to the elaboration of the detailed requirements of identification of living modified organisms that are intended for direct use as food or feed, or for processing, including:

> *(a) The documentation to accompany living modified organisms that are intended for direct use as food or feed, or for processing for the purpose of Article 18, paragraph 2 (a);*
>
> *(b) The information provided in the accompanying documentation;*

Australia supports documentation requirements that are:

- Minimally disruptive to trade by taking account of and being consistent with other international obligations, including WTO agreements;
- Not unduly burdensome or costly to implement or understand, from both the import and export perspective;
- Designed to meet the requirements explicitly set out in the Protocol and do not go beyond these requirements;
- Consistent with and avoid duplication of on-going work within existing international organizations, such as Codex Alimentarius Commission, International Plant Protection Convention and the Office International des Epizooties – which develop standards on the basis of sound science.

As such, Australia supports measures that would be able to be incorporated into existing documentation. It should be noted that exports of Australian grain are already accompanied by a number of documents – including bills of lading, Sanitary and Phytosanitary certificates, certificates of origin, banking documents, quality documents, stowage documents and always a commercial invoice. Australia believes that the existing documentation is sufficient to convey information requirements set down by the text of the Protocol for LMO-FFPs.

In that regard, Australia draws attention to the Executive Secretary's note prepared pursuant to a request by the WTO Committee on Trade and Environment (WT/CTE/W/235) in Special Session presenting an overview of decisions at MOP1 of relevance to the WTO. Australia particularly notes the Executive Secretary's characterization of the Decision BS-I/6 in relation to the documentation accompanying the transboundary shipment of LMOs: "In order to *avoid unnecessary burden to exports*, the first meeting of the Parties, in decision BS-I/6, decided to integrate identification requirements for LMOs for food, feed, and processing in commercial invoices or other relevant existing documentation systems."

Australia views that the first sentence of Article 18.2(a) provides for sufficient information to be placed on shipping documentation for fulfilling the objectives of the Protocol. It is important to recall that the key source of information on LMOs under the Protocol will be the Biosafety Clearing House (BCH). It is not intended that shipping documentation substitute for, or duplicate, the detailed information provided through the BCH.

(c) The extent and modality of using unique identifiers; and, if possible,

Australia is of the view that the requirement for unique identifiers has yet to be demonstrated. As Article 18.1 specifies "necessary measures" rather than "measures", it remains to be demonstrated that unique identifiers are "necessary measures". Therefore, the case for unique identifiers should be put forward and discussed prior to the Open-Ended TEG considering the extent and modality of using unique identifiers to achieve the objectives of the Protocol.

The second sentence of 18.2(a) is procedural in nature. '*[S]pecification of their identity and any unique identification…*' does not necessarily mean the use of unique identifiers. The question of whether unique identifiers are a "necessary measure" in this context is still open and to be resolved. Resolving the question needs to take into account countries' experience in implementing the Protocol and should be attempted via a step-wise approach:

- Assemble data that demonstrates the requirement for documentation identifying LMOs-FFP that are intended to undergo a transboundary movement
    - Assemble data that demonstrates how and in what circumstances documentation can assist in achieving the objectives of the Protocol
- Discuss this data
- Decide on whether identifying documentation is a "necessary measure"
- Discuss different ways of meeting a "necessary measure", including mechanisms that may already exist.

It should be noted that use of any documentation-based unique identifiers for intentional transboundary movements of LMOs-FFP needs to consider and resolve the following practical implementation issues:

- As the text of the Protocol provides only for identification of those LMO varieties intended to be contained in a shipment, what would happen if the identified list were inaccurate or incomplete?
- Is it envisaged that any unique identification be verified or subject to compliance or liability and redress measures? If so, how?

Regarding the OECD unique identifier system, Australia notes that it is focused on LMO plants, does not cover LMO microbes, animals or viruses and therefore has insufficient scope for use in the Protocol. Further, the veracity and robustness of the information is not guaranteed and the use of the system is not standardized.

Australia believes that adapting or seeking to harmonize other identification systems that cover LMO animals, microbes and viruses with the OECD system would be cumbersome and inefficient.

In addition, applying the OECD unique identifiers for Article 18 2(a) is limited, as:

- The OECD work on unique identifiers is voluntary and at an early stage of development.
- The use of unique identifiers is not standardised.
- The veracity of the information on the unique identifier database is not guaranteed.
- The range of products to which unique identifiers currently apply covers more than LMOs. How would the difference in coverage be resolved?
- There is no regulatory body that has considered adopting unique identifiers, nor administering their application or use. The CBD and subsidiary bodies, such as those associated with the Protocol, are not an appropriate regulatory body for this task – nor should it take on this role, as such a role would entail the setting of standards in an area in which it lacks suitable expertise and would be better dealt with elsewhere.

- The unique identifiers apply only to plants, whereas animal and micro-organisms are also within the scope of the Protocol. Therefore, the unique identifiers have insufficient scope.
- The use of unique identifiers would represent additional documentation and would be an additional cost on industry – without any gain for industry.
- The format of use of unique identifiers is not decided.

(d) Thresholds for adventitious or unintentional presence of LMOs that may be needed to trigger identification requirements;

Australia continues to hold the view that the text of the Protocol does not cover or apply to the adventitious or unintended presence of LMOs in non-LMO shipments as the text of Article 18.2a explicitly refers to LMOs *intended for* direct use as FFP. Providing guidance on the documentation of a shipment of conventional grain in relation to any possible or potential adventitious presence of LMOs, for example, is not within the scope of the Protocol.

Appropriate international standards-setting bodies, such as the International Plant Protection Convention and Codex Alimentarius are undertaking relevant work on thresholds of LMOs in conventional commodity shipments.

(e) Review available sampling and detection techniques, with a view to harmonization.

The Open-Ended TEG should bear in mind that there currently exist a range of sampling and testing technologies that can be used to detect the presence of LMOs. Each test has its own strengths and weaknesses. Therefore, the method that is most suited for each LMO must be determined on a case-by-case basis. There is considerable existing work in developing frameworks for harmonisation of tests for LMOs, such as the work of the Codex Committee on Methods and Analysis of Sampling.

(c) Information on experience with the use of existing unique identification systems under the Protocol, such as the Unique Identifier for Transgenic Plants of the Organization for Economic Co-operation and Development.

See the comments made on unique identification in 1c above.

BULGARIA [25 JUNE 2004]
[SUBMISSION: ENGLISH]

Bulgaria has no experience in activities like handling, transport, packaging and identification of LMOs, because up to now such organisms have never been imported in the country for direct use as food or feed, or for processing.

Provisions in the Draft on GMO Act (passing the second reading in our Parliament at the moment) require save transport, handling and packaging of LMOs.

Traceability and labeling requirements for products consisting of or containing GMOs and food and feed produced from GMOs are incorporated in the Draft, according to the Regulation (EC) No1830/2003.The operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

- that it contains or consist of GMOs
- clearly identified intended use
- the unique identifier assigned to those GMOs

– the contact details for further information

The Bulgarian draft of GMO Act is harmonized with the Commission Regulation (EC) No 65/2004 requiring establishment of a system for the development and assignment of unique identifiers for GMOs for placing on the market.

For products intended for direct processing, traceability and labeling requirements shall not apply when certain traces of GMOs may be adventitious or technically unavoidable. Such presence of GMOs should be no higher than 0.9%.

We support common formats for accompanying documentation with Article 18.

CAMEROON

[30 JUNE 2004]
[SUBMISSION: ENGLISH]

a) Cameroon has no practical experience in the implementation of the requirements of the first sentence of paragraph 2a. However in the Cameroon biosafety national legislation, the Law has interpreted the statement "may contain" to mean "containing LMOs or products thereof"

b) In addition to the information required for food quality control measures and that contained in Annex II of the Cartagena Protocol on Biosafety and what is already accepted under Sections 18 (2)(b&c) at the COP/MOP1, information should also be provided by the producer/developer on the allergenicity, toxicity, source of the gene, resistance to antibiotics of the LMO, if any.

c) Cameroon has not yet had any practical experiences in the use of the Unique identification system under the protocol especially the OECD Unique identifier for transgenic products. However common sense requires that the organism should be identifiable without any confusion worldwide as being the same and carrying the same genes and characteristics.

CANADA

[30 JUNE 2004]
[SUBMISSION: ENGLISH]

1. Canada is a large producer of grains, oilseeds, pulses and other crops, and has been a traditional supplier of agricultural commodities since the early part of the 20th century. The vast majority of these commodities are destined for use as food, feed or for processing.

2. Canada's reputation as a quality supplier of agricultural commodities is largely attributable to two factors: grading regulations that enable Canadian farmers to meet importers' needs, and an efficient bulk handling system which allows Canada to compete globally despite the vast distance from production areas to export terminals. Canada is committed to ensuring that Canadian agri-food products destined for food, feed or for processing are traded in a safe and responsible manner in order to meet the food requirements of importing countries. As a producer, consumer, exporter, and importer of agriculture products, Canada traditionally has supported science-based regulation both domestic and internationally.

3. Canada signed the Biosafety Protocol in April 2001, in support of its environmental objective. However, Canada indicated that clarity was needed on several key provisions in order for Canada to support ratification of the Protocol. As it is not a Party to the Protocol, Canada has not promulgated domestic legislation to implement the Biosafety Protocol (BSP), including the requirements of Article 18. Nevertheless, Canada is committed to working with Parties and Non-Parties to the Protocol to

clarify key provisions of concern by providing information on agricultural production, handling and exporting systems that can be used to facilitate the safe and responsible transboundary movements of LMOs. Canada has shown its' commitment to the BSP by developing the Canadian Node of the Biosafety Clearing-House (BCH), an essential component of the BSP which will contribute to the implementation and effectiveness of Article 11 and 18. The Canadian Node of the BCH is being completed so that countries of import may access information about Canada's domestic regulatory decisions on specific LMOs.

4. Canada welcomes this opportunity to provide views and comments on the requirements of Article 18 of the Biosafety Protocol.

(a) Information on Canada's experience in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18.

5. To protect Canada from the potential risks posed by new substances, Canada has a domestic regulatory system for all new substances. The scope of these regulations includes living modified organisms such as plants, microorganisms, etc. Further information on Canada's regulatory framework can be found on the Canadian node of the Biosafety Clearing-House.

6. Canada has gained experience on the handling, transport, packaging and identification of LMOs for food, feed or for processing as an exporter and importer of LMOs. Currently, the only LMOs either exported or imported for food, feed or for processing are of plant origin. Therefore, the content of this submission will be focused on plant LMOs.

7. To protect Canada from the potential risks posed by novel plants, Canada has in place a domestic regulatory system for plants with novel traits (PNTs) which ensures that the introduction of new crop varieties does not have adverse effects with regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity. In Canada, PNTs may be produced by conventional breeding, mutagenesis, or by recombinant DNA techniques.

8. Canada's regulation of PNTs is triggered by the PNT's characteristics and its novelty in Canada, not by the process by which it was developed. Environmental safety assessments are required for all PNTs intended for importat and/or for environmental release in Canada, including those intended for food, feed or processing. Safety assessments of livestock feeds and foods derived from biotechnology are also required in Canada prior to approval for placing on the market. Approvals for unconfined environmental release, novel feed and novel food are concurrent. The LMO status of a PNT is not relevant to decisions regarding importation to Canada. Decisions on importation are rather related to the approval status of products in the shipment.

9. LMOs of corn, canola and soybeans, among other crops, have so far been approved for unconfined environmental release in Canada. As countries begin to submit information regarding approvals of LMOs onto the BCH and if Canada imports that commodity, Canada will ensure that an appropriate risk assessment will be conducted and the LMO approved before importers can import the product. A list of the decision documents related to the approval of LMOs in Canada can be found on the Canadian Node of the Biosafety Clearing-House.

10. Canada participated in the three Intergovernmental Committees on the Cartagena Protocol (ICCP) and the technical expert group meetings on Article 18 to develop practical and pragmatic documentation measures for LMOs destined for food, feed or processing (FFP). Unfortunately, these initiatives did not generate consensus on all aspects of the specific documentation requirements and as such, certain elements of the documentation provision remained unclear when the Protocol entered into force in September 2003.

11. Part of Canada's experience with the implementation of the requirements of the first sentence of paragraph 2(a) is related to its initiative to clarify the documentation requirements for exporters and importers of FFP LMOs. To this end, in October 2003 Canada entered into a North American Trilateral

Arrangement with Mexico and the United States to clarify and provide guidance to agriculture commodity producers and handlers regarding the documentation requirements for agriculture commodities. Canada undertook this initiative in anticipation of the entry into force of the BSP prior to MOP-1.

12. The documentation provisions of the North American Trilateral Arrangement are compatible with the recommendations of a technical experts meeting on Article 18 which took place in Montreal, Canada in March, 2002. The provisions of the arrangement identify the trigger for documentation, the specific "may contain" language and the document on which the "may contain" language should be applied. In practical terms, the "may contain" documentation would be applied on all shipments of Canadian canola and corn intended for use a food, feed or for processing because LMO varieties of these commodity species have been approved in Canada and have not been segregated from non-LMO varieties. Documentation has not been applied to a portion of soybean exports as shipments of these varieties have been grown and handled under Identity Preserved 1/ conditions, as contractually agreed between buyers and sellers. The "may contain" documentation will not apply to Canadian shipments in which Canada does not have in commerce any LMOs of those species.

13. The provisions also specify who should be the "contact points" in order to obtain further information on the LMO.

14. Relevant excerpts of the North American Trilateral Arrangement are identified below, with annotations relating to implementation under Article 18.2(a) first sentence.

(b) Canada's views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18, including specification of the identity of the living modified organisms that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of living modified organisms with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification.

15. Canada's stringent regulatory framework for Plants with Novel Traits (PNTs), including plants that are novel LMOs, does not include documentation requirements. Canada does require notification and assessment of all PNTs, including novel LMOs prior to import. Following approval, these LMOs have the same status as any other product. Unapproved or conditional approvals are identified to the customs officials prior to any import. Under these conditions therefore, as an importer, Canada has no experience with documentation at this time. As an exporter, given that the majority of Parties have not put in place documentation requirements at this time, Canada has limited experience in this regard as well.

16. Canada agrees with the documentation requirements outlined in Article 18.2(a) of the Protocol indicating that a shipment "may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment". However, throughout the negotiations surrounding the Protocol, Canada consistently articulated the need for Parties to gain experience with implementing the first sentence requirements on documentation prior to considering what additional requirements might be necessary to achieve the objective of the Protocol.

1/ Identify Preserved commodities command a higher price to reflect increased costs in producing, transporting, handling and storing the commodity. These higher costs reflect the use of dedicated farm, storage and transportation equipments; and testing and sampling throughout various points in the production and transportation, as may be required. Additional costs for pesticides and herbicides, and/or lower yields may apply. IP shipments account for a very small percentage of overall Canadian agricultural commodity shipments.

17. All the necessary information on LMOs for food, feed or processing can be located on the Biosafety Clearing House. Should the experience gained under the Protocol demonstrate a clear need and benefit for additional requirements, Canada is open to revisiting this position.

18. In the meantime, should any country require additional information, which would of course differ from country-to-country depending on their risk profile and the products they import, Canada is prepared to engage in technical discussions between regulatory authorities on how to best address their specific requirements. Indeed, such discussions may be beneficial in clarifying the needs of importing countries and how these could be addressed in a manner that could inform future discussions on the Protocol requirements.

(b ii) Canada's views regarding possible linkages of the issue with Article 17 of the Protocol;

19. A Party is required to notify affected States when it becomes aware of an occurrence under its jurisdiction resulting in a release that leads or may lead to an unintentional transboundary movement of an LMO that is likely to have a significant adverse effect on biodiversity in a receiving country. It would appear, however, that this obligation would not pertain to adventitious presence (unintentional, technically unavoidable presence of a LMO) in transboundary shipments of commodities intended for food, feed or processing, given that these shipments are not intended for introduction into the environment. Since FFP shipments are not intended for introduction into the environment, adventitious presence in LMO FFP shipments would not be included within this provision.

(c) Their experiences with the use of existing unique identification systems under the Protocol, such as the Unique Identifier for Transgenic Plants of the Organization for Economic Co-operation and Development.

20. The Organisation for Economic Co-operation and Development (OECD) has developed the only currently existing internationally recognized system for unique identification of transgenic plants. As a member of the OECD and an active participant in the Working Group on Harmonisation of Regulatory Oversight in Biotechnology that developed the unique identifier, Canada has agreed to implement the OECD system. Canada requires that developers of transgenic plant products submit unique identifiers in their Applications for Determination of Environmental Safety. Since instituting this requirement, all submissions for environmental release have included the designation of a unique identifier for the transgenic event. Further, product development companies have retroactively provided unique identifiers for products that previously have been granted authorization for unconfined environmental release. Currently, unique identifiers for LMO plants are used primarily by Canadian regulators in discussions with regulators from other countries, as they are a unique point of reference for a given product. The OECD unique identifiers for LMO plants are not used in any transactional context.

21. The OECD is currently exploring the possibility of developing unique identification systems for non-plant LMOs. With respect to micro-organisms, the OECD has not yet developed a UI scheme. Under the Canadian domestic regulatory system, proponents are required to uniquely identify a notified micro-organism in order that it may be distinguished for regulatory purposes. Culture collection accession numbers, from both internationally recognized collections as well as company-specific collections, have been used for this purpose. While this system has served its purpose to date, it is recognized that this system is not harmonized in that a given LMO may be deposited in more than one culture collection and consequently may have more than one accession number. However, in any given culture collection, the accession number is unique.

Notes regarding the text of the Arrangement 2/:

"*Article 18.2(a) of the BSP will be implemented as follows:"*

2/ The full text of the North American trilateral arrangement is available at the following URL, or in hard copy from the Canadian National Focal Point. http://www.agr.gc.ca/itpd-dpci/english/topics/bsp_trilateral.htm

"The 'may contain' language, when included as per section 4 below, should appear on the commercial invoice as provided by the exporter. The importer is responsible for receiving the invoice and maintaining it after entry."

22. The commercial invoice was identified as the appropriate document in which the "may contain" language should be provided for a number of reasons: i) the document accompanies all commodity shipments; ii) the documentation system is used internationally not just between Parties; iii) port officials are familiar with the commercial invoice; iv) developing another documentation system would require additional financial resources and would take additional time to develop; and v) importers in Canada must ensure that the information on the document is factual and correct under the *Canada Customs Act and Regulations*. However, until the "may contain" language becomes a regulatory requirement by an implementing federal department or agency within Canada, the Customs' requirements for a detailed invoice description will not cover this "may contain" language requirement.

"The 'may contain' language, when included, should state:"

"Cartagena Biosafety Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

The "may contain" language was recommended by the technical expert group on Article 18 in Montreal.

The last exporter prior to the transboundary movement and the first importer after the transboundary movement are to be named on the invoice and are the contact points for further information.

23. The last exporter and the first importer were identified as the appropriate contact points because: i) the first importer has the contact information of the last exporter; and ii) the last exporter obtains the necessary information related to the LMO; or ii) the last exporter knows how to obtain the necessary information.

"Applicability":

a. "The 'may contain' documentation will be used for all transboundary movements of commodities intended for food or feed, or for processing, where an LMO of that commodity species is authorized[3] *in, or sold from, a country of export, except:"*

(i) "Shipments for which the exporting country does not have in commerce any LMO of that species; or"

(ii) "When the exporter and importer have contractually defined a "non-LMO shipment;" provided, that such a shipment achieves a minimum of 95 percent non-LMO content, and that such definition does not conflict with regulations of the importing country."

b. "Adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation."

24. The above language was developed to clarify what shipments require documentation, i.e., the 'trigger' for documentation. In practical terms the exporter must i) use the BCH (the Canadian Food Inspection Agency website has been used in the interim prior to the BCH becoming active) to determine if an LMO of that commodity species is approved in Canada. If an LMO of that commodity species is listed on the BCH there is the possibility that there is an LMO variety of that commodity species in commercial production; ii) determine if the LMO is in commercial production by contacting

3/ Approved for unconfined release (Canada), deregulated (United States), or approved (Mexico), noting that the Biosafety Clearing House is an important reference tool.

the producer associations; and iii) determine if the commodity has been effectively segregated (95% purity) from LMO varieties of that commodity species. If an LMO has been granted regulatory approval, is in commerce and has not been effectively segregated then that shipment would require the documentation.

25. This *minimum* 95% non-LMO purity standard was established to provide clarity as to what shipments required documentation, provided that the contractual arrangement does not conflict with the regulations of the importing country. The 95% purity standard was developed in order for producers and exporters of identity preserved commodities to avoid applying the "may contain" documentation on shipments destined for food, feed or for processing. As such, this would avoid confusion when the contractual arrangement between the exporter and importer stipulated that the commodities are identity preserved and therefore, do not contain the "may contain LMOs" documentation.

26. Canada's experience, to date, regarding Article 18.2(a) is primarily related to developing the North American Trilateral Arrangement. Negotiating the arrangement has provided an opportunity for Canada to help develop clear and practical guidance on how to document LMO shipments destined for FFP, and facilitate exporters' ability to implement documentation.

27. Canada has shipped 350,000 Tonnes of canola to Mexico since November 2003. Zero shipments of maize and soybeans to Mexico have been exported from Canada since November 2003. The Government of Canada has been in communication with industry associations regarding the documentation and according to the export companies, documentation has accompanied shipments of canola to Mexico. No canola shipments destined for Mexico have been detained or rejected.

COLOMBIA

[13 JULY 2004]
[SUBMISSION: SPANISH]

1. lnformación sobre experiencias, si existen, en la implamenteción de los requerimientos da la primera frase del párrafo 2 (a) del articulo 18 del Protocolo.

"Cada parte adoptará las medidas para requerir que la documentación que acompaña a: OVM destinados a uso directo como alimento humano o animal o para procesamiento, identifica claramente que "puede ilegar a contaner" OVM y que no estan dostinados para su introducción intancional en el medio, asi como un punto de contacio para solicitar información adicional".

En Colombia, existe una reglamentación vigente en materia de documentación para OVM destinados para alimento humano, y para uso agricola y pecuario. En primer lugar, el Decreto 3075 de 1997 del Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA, establece en su articulo 54 que a los alimentos obtenidos por biotecnologia de tercera generación y lo procesos de ingenieria genética, se les otorgará Registro Sanitario previo estudio y concepto favorable de la Comisión Revisora - Sala Especializada de Alimentos, conforme a lo establecido en el Decreto 0936 de mayo 27 de 1996, o los que los sustituyen, adicionen o modifiquen. El registro sanitario, en el caso de OVM destinados a alimento humano y que van a ser importados, debe incluir la siguiente documentatión:

1. Formulario de solicitud de Registro Sanitario en el cual se consignará la siguiente información:

1.1 Nombre o razón social de la persona natural o juridica a cuyo nombre se solicita el registro sanitario y su domicilio.

1.2 Nombre o razon social y ubicación del fabricante

1.3 Nombre y marca (s) del producto

1.4 Descripción del producto

2. Certificado de existencia y representación legal del interesado, cuando se trate de persona juridica o matricula rnercantil cuando se trate de persona natural.

3. Certificado expedido por la autoridad sanitaria del país exportador, en el cual conste que el producto está autorizado para el consumo humano y es de venta libre en ese país.

4. Constancia de que el producto proviene de un fabricante o distribuidor autorizado, salvo cuando el titular del registro sea el mismo fabricante.

5. Recibo de pago por derechos de registro sanitario establecidos en la ley.

Además, se subraya que los alimentos importados deben cumplir con las norrnas técnico-sanitarias expedidas por el Ministerio de Salud, las oficiales Colombianas o en su defecto con 1as normas del *Codex Alimentarius*.

Igualmente, todo lote o cargamento de alimentos que se importe a Colombia, debe ir acompañado del respectlvo certificado sanitario o su equivalente expedido por la autoridad sanitaria competente, en el cual conste que los alimentos son aptos para el consumo humano. Todo lote o cargamento de alimentos o materias primas objeto de importación, requiere para tal proceso del certificado de inspección sanitaria expedido por la autoridad sanitaria del puerto de ingreso de los productos.

Asimismo, para la expedición del certificado de inspección sanitaria para la nacionalización de alimentos y materias primas para alimentos se requiere:

a. Certificado sanitario del país de origen o su equivalente.

b. Copia del registro sanitario para aquellos productos que estén sujetos a este requisito según lo establecido en este decreto.

c. Acta de inspección de la mercancía.

d. Resultados de los análisis de laboratorio realizados a las muestras de los productos.

Además de la reglamentación del INVIMA que es exclusiva para alimentos destinados al consumo humano, el Instituto Colombiano Agropecuario, ICA, a través de su Resolución 03492 de 1998, por la cual se raglamenta y se establece el procedimiento para la introducción, producción, liberación y cornercialización de Organismos Modificados Genéticamente (OMG)4 y se dictan otras disposiciones, en su Capitulo IV, articulo 11, establece que "Para su comercialización, las semillas, plantas y demás material de reproducción destinado para siembra y que sean OMG, deberán tener impreso en el rótulo o etiqueta claramente visible la siguiente frase: "ORGANISMO MODIFICADO GENETICAMENTE".

Por otre parte, el articulo 27 de la misma resolución establece que: "Además de los requisitos establecidos en la presente resolucoón para la importación y comercialización de OMG de origen vegetal se deberá cumplir todas las normas siguientes relacionadas con:

- Nombre del producto y nombre del OMG quo contengan.
- Nombre y dirección del fabricante o distribuidor.
- Especificidad del producto.
- Condiciones de uso, tipo de uso previsto.
- Medidas a adoptarse en caso de liberación no intencionada o de uso indebido.

4/ Es necesario aclarar que esta resolución solamente cobija los OVM para uso agricola.

- Instrucciones o recomendaciones especificas de almacenamiento y manipulación.
- Envase propuesto, etiquetado propuesto"

Además, la Resolución ICA 02935 de 2001, por la cual se reglamenta y establece el procedimiento de bioseguridad para la introducción, producción, liberación, comercialización, investigación, desarrollo biológico y control de calidad de Organismos Modificados Genéticamente, OMG, de interés en salud y producción pecuaria, sus derivados y productos que los contengan, también contempla medidas de acuerdo con el párrafo 2 a del articulo 18 del Protocolo:

"Articulo 14. Para su comercialización, los insumos pecuarios y demás material de uso animal que sean OMG, deberán tener impreso rótulo o etiqueta claramente visible con la frase "ORGANISMO MODIFICADO GENÉTICAMENTE".

"Articulo 67. Para todos los casos de transporte de OMG descritos en los articulos anteriores los empaques deben estar claramente identificados con los símbolos de bioseguridad y de fragilidad, con la siguiente leyenda: "Solo puade abrirse en el laboratorio por personal especializado". En el empaque externo debe identificarse el nombre, la diracción completa y el teléfono, del destinatario y del remitente"

"Articulo 90. Se prohibe la liberación al medio ambiente de animales no rnodificados genéticamente que se encuentren donde se manipula OMG".

Si bien en el país existe una reglamentación bastante completa sobre la documentación de los Organismos Vivos Modificados (OVM), hasta la fecha no se han presentado situaciones en las que se requiera una documentación anexa que acompañe a estos organismos bien sea que éstos sean destinados al uso como alimento humano o para su procesamiento y que a su vez, no estén destinados para la introducción intencional en el medio.

2. Puntos de vista ralacionados con los requerimientos detallados que están contenidos en la segunda frase del párrafo 2 (a) del articulo 18, Incluyendo especificación sobre la Identidad de OVM de uso directo para alimentación, procesamiento o siembra (donde la extensión de la información debe contener nombre taxonómico, las modificaciones insertas al gen y los cambios genéticos): niveles umbral en el caso de mezcia entre OVM y no OVM y posibles lazos de este tema con el articulo 17 del Protocolo; el lenguaje "puede contener"; y la identlficación única.

“La Conferencia de las Partes, en su calidad de reunión de las Partes en el presento Protocolo, adoptara una decisión acarca de los requisitos pormenorizados para este fin, con inclusión de la especificación de su identidad y cualquiera identificación exclusiva, a mas tardar dos años despues de la fecha de entrada en vigor del presente protocolo.”

Para los países importadores es básico conocer los detalles especificos del OVM que va a ser introducido al país. Es indispensable el etiquetado, por lo menos, de OVM destinados a consumo directo humano o animal, como material prima para procesamiento y para liberación intencional al medio ambiente. Esto permite garantizar una minima seguridad respecto a un minimo mecanismo de control a los principales OVM que ingresan o ingresarán al país. La Conferencia de las Partes deberia tener en cuenta que debe existir una información minima que contenga la etiqueta para OVM, ya sea que estos estén mezclados o no. Si “puede contener" o "contiene" OVM, deben ir con mayor especificidad los datos del OVM que sean de relevancia como: si es mezcla y en que porcentaje se encuentra, clasificación taxonómica del OVM, tipo de modificación, finalidad de la importación, grado de alergenicidad o toxicidad encontrado, etc. De todas maneras, en los documentos de importación que acompañan a la carga, deberá, tanto para detal como para granel, especificarse la información completa del OVM, de acuerdo con lo solicitado por ei país importador. Para ello se eatablece la necesidad de definir, métodos de detección, verificación, muestreo y análisis, que puedan ser estandarizados y compatibles a nivel internacional. En este sentido, se

hace también imperiosa la necesidad de capacitación a técnicos de los diferentes sectores (alimentos, medio ambiente, agricultura, aduanas etc.) respecto a la aplicación y utilización de dichos sistemas.

En cuanto al lenguaje "puede contener", de acuerdo con la legislación nacional (punto 1), todo OVM que se introduzca al país obligatoriamente debe estar rotulado como "Organismo Genéticamente Modificado", sin especificar su grado de mezcla o modificación. El lenquaje aprobado por el Protocolo es un minimo estándar internacional, con la posibilidad de dejar a los países importadores establecer términos más precisos de rotulado para el ingreso de OVM a sus territorios. En Colombia, actualmente se está en proceso de desarrollar normativas sobre importación de material que pueda contener OVM.

3. Información sobre experiencias con el uso de sistemas existentes de identificación única bajo el Protocolo, como el Identificador Unico para Plantas Transgénicas de la Organización para la Cooperación Económica y e1 Deserrollo (OECD).

En Colombia actualmente no se tienen experiencias al respecto.

EUROPEAN UNION [29 JUNE 2004]
[SUBMISSION: ENGLISH]

Decision BS-I/6 of the First Meeting of the Parties (MOP1) to the Cartagena Protocol requests views on Article 18(2)(a). Paragraph 7 of Part A of the Decision reads as follows:

"*Requests Parties to the Protocol, other Governments and relevant international organizations to provide to the Executive Secretary by 30 June 2004:*

(a) Information on their experience, if any, in the implementation of the requirements of the first sentence of paragraph 2 (a) of Article 18; and

(b) Their views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18, including specification of the identity of the LMOs that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification;

(c) Their experiences with the use of existing unique identification systems under the Protocol, such as the OECD Unique Identifier for Transgenic Plants;".

The EU already submitted its views on this provision on two occasions: in 2002, in preparation for ICCP3, and in 2003, in preparation for MOP1. The text of these submissions is available on the CBD website among the background documents for those meetings.

Therefore, the purpose of this paper is succinctly to recall the EU's views on this matter, having particular regard to the outcome of MOP1, while highlighting the most recent developments in the EU legislative framework. This submission addresses the three parts of the request for information in turn.

***(a)* Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18**

The EU has always maintained that there is a clear and logical link between the first and second sentence of Article 18(2)(a). MOP1 recognised this and made progress in the development of requirements which clarify this provision.

The EU has developed a comprehensive legislative framework on GMOs, which also addresses the issue of documentation requirements for LMOFFPs covered by Article 18(2)(a).

The EU recently adopted three legal acts relevant to the implementation and operation of the Cartagena Protocol on Biosafety:

- *Regulation (EC) No 1946/2003 on Transboundary Movements of Genetically Modified Organisms;*
- *Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed;*
- *Regulation (EC) No 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms and amending Directive 2001/18/EC.*

The text of these Regulations is available on the Protocol's Biosafety Clearing House (BCH).

The three Regulations entered into force in 2003. The latter two have been applicable since mid April 2004. Two implementing Regulations in this area[5] also took effect in April 2004. The Community has put in place an exhaustive set of requirements concerning the identification of LMOs, for any use foreseen in Article 18(2) of the Protocol. The EU considers that, in order to provide adequate information to importers of LMOs in third countries, it is appropriate to impose similar requirements on operators exporting LMOs from the EU and on those using LMOs within the EU.

In relation to Article 18(2)(a), the EU wishes to recall that, under Article 12 of the EC Regulation on Transboundary Movements of GMOs:

1. exporters are required to ensure that the following information is stated in a document accompanying the GMO and is transmitted to the importer receiving the GMO:

a) that it contains or consists of GMOs, and

b) the unique identification code(s) assigned to those GMOs, if such codes exist; and

2. for GMOs intended for direct use as food or feed, or for processing, the above information must be supplemented by a declaration by the exporter:

a) stating that the GMOs are intended for direct use as food or feed, or for processing and indicating clearly that they are not intended for deliberate release into the environment, and

b) giving details of the contact point for further information.

The requirements under 1(b) above do not apply to products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing. These products are subject to the Regulation on traceability and labelling of GMOs.

5/ Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 and Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs.

Under the latter Regulation, business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market. In particular, the requirements are that:

- operators are to have systems and standardised procedures in place to identify to whom and from whom products are made available;

- in the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, written information on the unique identifier(s) assigned to the GMOs of which the product consists or which are contained in it, may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

The provisions on identification of LMOs as set out in the Regulations on Transboundary Movements and on Traceability and Labelling of GMOs are without prejudice to other specific requirements imposed by Community legislation and international identification requirements to be developed in accordance with Article 18 of the Protocol.

Moreover, the EU internal standards are subject to review on the same (two-year) time scale as the determination of detailed requirements under the Protocol for the purposes of Article 18(2)(a). This review will take account of any detailed requirements agreed by Parties to the Protocol on identification of LMOs.

More information on the content of these Regulations, including a description of labelling and traceability rules can be found in "Questions and Answers on the regulation of GMOs in the EU" on the Europa Website at:
http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/04/85|0|RAPID&lg=EN&display=.

(b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18, including specification of the identity of the LMOs that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification

This request for information contains five different elements: 1) specification of the identity of LMOFFPs; 2) threshold levels in case of commingling with non-LMOs; 3) linkages with Article 17; 4) the "may contain" language; and 5) any unique identification.

Parties to the Cartagena Protocol have already addressed some of these issues at MOP1 by adopting Decision BS-I/6 which operationalised the existing requirements under Article 18(2)(a) of the Protocol. Shipments of LMOFFPs are to be accompanied by a commercial invoice or other documents to specify that the shipment "may contain" LMOs and is not intended for introduction into the environment. A contact point (the importer, exporter or any appropriate authority) should also be included. In addition, the decision expands on existing requirements by 'urging' Parties and other governments to require information on the name of the organism (common, scientific and, where available, commercial name) and the transformation event or, where available, the unique identifier code as a key to accessing information in the Biosafety Clearing House. Moreover, the decision encourages Parties to require that exporters specify, in documents accompanying transboundary movements 'known to intentionally contain LMOFFPs', that the shipment contains LMOFFPs, the identity of the LMO, and any unique identification, where possible. Finally, the decision invites Parties to apply the OECD Unique Identifiers

for Transgenic Plants to living modified plants under the Protocol and requests that the Secretariat develop in the BCH a register of unique identification codes. It also encourages the OECD to work towards the development of unique identifiers for GM micro-organisms and animals.

Therefore, Decision BS-I/6 already addresses points 1, 4 and 5 above to some extent, providing concrete ways of implementing Article 18(2)(a). The EU continues to support that decision and has put in place, in its legislative framework referred to above, requirements that are fully compatible with it. Moreover, the EU considers that it could be helpful for documentation to specify both the transformation event and the unique identifier until operators become more acquainted with the unique identifiers system. Some national authorities are still more familiar with the transformation event and may not have access to the BCH in the short term.

The EU believes that Decision BS-I/6 should indeed be confirmed and further developed, including with regard to points 2 and 3 above, with a view to adopting 'detailed requirements' within two years from the entry into force of the Biosafety Protocol (i.e., at MOP2) as Article 18(2)(a) requires. This would allow importing countries to verify that imported LMOFFPs are those that they agree to import.

In that context, the EU is firmly convinced that an international exchange of views and experience is necessary and that capacity building should be enhanced. The workshop on capacity building and the exchange of experience on the safe handling, transport, packaging and identification of LMOs (planned to take place in November 2004, before the first meeting of the open-ended technical expert group) will make an important contribution to the achievement of that goal and the EU therefore fully supports it. In addition, the EU proposes further to explore the possibilities for, and content of, documents for LMO shipments.

In relation to point 2 above, on thresholds in case of commingling with non-GMOs, the EU believes that the issue of thresholds should indeed be addressed in relation to Article 18(2)(a) of the Protocol. The EU would like to recall that, under EC law, the traceability and labelling requirements of GMOs intended for direct use as food, feed or for processing do not apply to trace amount of authorised GMOs no higher than a threshold of 0.9%, provided that these traces are adventitious or technically unavoidable. Moreover the EU has set a specific threshold of 0.5% for GMOs which have not been authorised according to EU rules but received a favourable opinion from the Community Scientific Committee(s) or the European Food Safety Authority before April 2004.

Finally, with regard to point 3 above and linkages with Article 17, the EU believes that the scope of Article 17 covers *all* LMOs likely to have significant adverse effects on the conservation and sustainable use of biodiversity taking into account risks to human health in affected or potentially affected States.

(c) Their experiences with the use of existing unique identification systems under the Protocol, such as the OECD Unique Identifier for Transgenic Plants

The EU has adopted the format developed by the OECD for Unique Identifiers for Transgenic Plants, to be implemented as part of its own regulatory framework for GMOs.6 Moreover, it has extended use of this format to unique identifiers for genetically modified micro-organisms and animals pending the development and adoption of any other specific format at an international level. The use of the OECD format for unique identifiers became mandatory on 15 April 2004.

6/ See Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs.

As mentioned above, the EU supports the use of the unique identifier as a key to access information available on the Biosafety Clearing House. The EU further suggests that it might be helpful for documentation specifying the unique identifier also to quote the internet address of the BCH, to facilitate access to additional information.

GUINEA BISSAU [28 JUNE 2004]
[SUBMISSION: ENGLISH]

a) *Information on experience, in implementation of the requirements of the first sentence of paragraph 2 a) of article 18.*

We do have no information on experience about usages or importing any kind of LMOs or its derivate or co-mingling of LMOs used directly as FFP in the country. In the past, may be until 1998. But we are not now in condition to give information about it. Since the LMO and GMO are new for the country.

b) *Views regarding the second sentence of paragraph 2 a) of article 18*

All question related with the handling, transport, packaging and identification of any Products that may containing LMO or its products Intended for FFP, use in our opinion must have all information us presented at the decision BS/1/6 with all details.

And not only but to urgent assist the country like ours to be ready technical, and materially (equipments and laboratory, human resources) to have the scientifically support to take the decision, when necessary, based in scientific manner.

c) *Information concerning experience on the use of unique identification systems under the Protocol.*

The country had signed the Protocol, and no ratification had taken place till today.

The pilot phase of the project of the national framework of the Protocol is approved, and signed, officially on past February. Every thing concerned with the Protocol is new and we have just started with the project, and having no time to get all information about such important things at national level.

Anyhow concerning unique identifier for transgenic plants of the organization for cooperation and development, (OECD) the national institution involved in it have nothing about it. Everything involved with transgenic plants is new for us.

So it is urgent to start with the LMO capacity building at national level. Essentially about risk assessment and risk management, and the concerned with the article 18 of the Protocol.

INDIA [21 JULY 2004]
[SUBMISSION: ENGLISH]

1. Information on experience, if any, in the implementation of the requirement of the first sentence of Paragraph 2 (a) of Article 18

1.1 In India, the Genetically Modified Organisms and Products derived there from are regulated under the **Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells 1989** notified under the Environmental Protection Act, 1986. These rules and regulations cover the areas of research as well as large-scale applications of GMOs and products made there from throughout India. The rules cover activities involving manufacture, use, import, export, storage and research. These rules also define the competent authorities for handling various aspects of the rules. The Rules also specify the information to be submitted by the importer.

1.2 Therefore import of any living modified organisms that are intended for direct use as food, feed or for processing under Article 18 (2a) would attract the provision of the Indian domestic regulations even if it is for contained use and "may contain" declaration. **2. Views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18, including specification of the identity of the living modified organisms (LMOs) that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs; and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification.**

2.1 Detailed requirements on the identity of LMOs-FFPs.

India is of the view that information should be provided to identify LMOs-FFP that may be contained in a given transboundary movement. India supports that information on the specific identity of the LMOs-FFP or unique identity, the host organism and the donor, the transformation event(s) involved, and a reference to accessing relevant information in the Biosafety Clearing-House should be supplied as "minimum" information in the document accompanying the shipment to facilitate scientifically-sound and transparent case-by-case assessments about whether the import of an LMO (or group of LMOs) would pose any risks to their biodiversity; and ensure appropriate risk management action if necessary (based on those assessment).

2.2 Adventitious/unintentional presence of LMOs and thresholds

2.2.1 It is generally agreed that thresholds have to be established for ensuring the practicability and feasibility of identification or labeling of a shipment of LMO-FFPs where adventitious or technically unavoidable traces of LMOs cannot be excluded, below which these LMOs would not have to be identified or labeled. Different countries have proposed various thresholds for LMO presence varying from 0.9% to 5%. There is no threshold established in India for seeking approval of GEAC or for labeling under our domestic regulations. Therefore, it is difficult for India at this stage to argue for a particular threshold limit. The issue would require evolving a national position before international position could be taken.

2.3 Identity Preservation

2.3.1 Identity preservation (traceability) is a procedure used to maintain and track the identity of a particular quantity of a commodity throughout the production and distribution chain. It is relevant to consider the issues of unique identification and adventitious presence of LMOs, because it provides information on the specific varieties of a commodity that could be expected to be present in a trans-boundary shipment.

2.3.2 The EU regulation on traceability and labeling of GMOs defines the traceability as maintenance and transmission of records from seeds to marketplace. However, identity preservation cannot be undertaken without causing a substantial increase in costs. In India, in case large scale commercial cultivation of GM crops takes place in future, it would be very difficult to ensure crop segregation and maintenance and transmission of records from seeds to market place due to large number of small farmers, mandi system and unorganized supply chain system. Therefore, India is not in favour of inclusion of any identity preservation requirements in the Bio-Safety Protocol.

2.4 Labeling

2.4.1 Mandatory labeling for packages of all LMO-FFPs and their products at the time of final sale to the consumer is not an issue under discussion in the Bio-Safety Protocol. The national position in India on this issue is still evolving. India has not mandated mandatory labeling domestically. This issue would require evolving domestic policy and national position, before an international position is taken.

2.5 Type of Documentation accompanying LMOs-FFPs.

2.5.1 Since commercial invoice is not controlled by the National Authority nor it is under the supervision of the Protocol, India prefers a stand alone document. However, we are willing to consider the existing documentation system if suitably customized to include the identification requirements of LMOs in FFPs. Some suggestions on the templates enclosed as Annexed document UNEP/CBD/BS/COP-MOP/1/15 page 91 to 97 of the report of the first meeting of the COP-MOP.

3. Information on experience with the use of existing unique identification systems under the Protocol, such as the Unique for Transgenic Plants of the Organization for Economic Co-operation and Development.

3.1.1 A unique identification system for LMOs based on a transformation event is essential for the efficient functioning of the decisions which form the database for the BCH. This is critical for tracking of decisions under Article 11.1 of the Protocol. The only available system is the OECD guidance for the designation of a unique identifier for a transgenic plant. A similar system may be developed for other groups of LMOs such as microorganisms and animals.
3.1.2 India welcomes the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants developed by the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology and now widely used within the OECD LMOs product database.

3.1.3 Scientifically, the unique identifier criteria for transgenic plants should be based on the information about the genes used, the promoters utilized, the terminator sequences used, the markers and the regulatory sequences for operationalizing them are used, the enhancer/suppressor genes used, the plants deployed for transformation as well as the transformation events.

3.1.4 It shall be the responsibility of the applicant who proposes to introduce transgenic plants or propagating substances produced there from like say seeds/fruits etc. into the open environment to provide full information as above on the substances.

3.1.5 To begin with, the unique identifier data shall contain at the minimum the name of the product including the scientific name as well as the common name and trade name where applicable, main trait of the substance like disease resistant or pest tolerant or herbicide tolerant etc., details about the genes and other transgenic nucleotide sequences inserted, methods of transformation event, linkage to biosafety data, information about whether the substance is approved anywhere and for what purpose of use, basis of

approval process elsewhere, detection process of the substance when in use, whether any special method of handling is required, packaging requirements, documentation procedures etc.

3.1.6 Such substances should be identifiable by simple digital code. Such codes need to be developed. All relevant safety information on such substances shall be generated by the applicant on the basis of guidelines, which is globally harmonized.

3.1.7 All data generated locally or obtained from outside sources shall be notified by the party on a national website which shall be accessible by persons desirous of knowing the status of specific products and events. The web site shall be linked with the Biosafety Clearing House of the CBD.

3.1.8 The public has the right to know what transgenic substance is in use in the country and on what basis the substance has been authorized for use in the country. The website therefore shall portray the basis of approval process. The website shall also give detail lists of transgenic substances that have been considered as safe and has been authorized for free use the country.

4. Additional Views on identification aspect and Capacity Building.

4.1.1 There is need for the deposition of authenticated voucher specimen in the National/regional Lab or institute for conforming the identity, when needed, and live reference collection as well for the conformity of the element.

4.1.2 The collection is to be preserved with the standard method of preservation typical of the centre or laboratory of origin or repositories.

4.1.3 There is need for the development/providing of diagnostic kit for the aid in identification of the specimen. To begin with a preliminary checklist on the elements and variability may be made.

4.1.4 Capacity building on the integrated aspects of the identification of the LMOs is required to be done at intergovernmental, inter-organization and interdisciplinary levels.

4.1.5 There is need for developing a classification based on the available database and potential parameters of indigenous and exotic nature. A computerized classification-cum-information system on LMOs intended for direct use for food, feed or for processing will aid in rapid assessment and evaluation of materials in the State of export.

4.1.6 Details of the identity, diagnostic features, precautionary measures over the potential risk, laboratories of the development and biological origin (phyto/zoogeographic entities) are required to be provided on the packages of LMOs to be transported. Geographical entities of LMOs would help in transboundary aspect of elements.

4.1.7 Extension and educational materials on the LMOs-FFPs emphasizing on the identification and diagnostics are required to be prepared.

UNEP/CBD/BS/COP-MOP/1/15

Annex

EXAMPLES OF INTEGRATION OF INFORMATION REQUIREMENTS INTO EXISTING DOCUMENTATION

For A: Blank Example of Template for Article 18.2 (b)

Table 2/Column 1 after phone at **official mobile No** also.

Table 4 under Column 4 (description) add after Name of the organization add **exchange** under Intended use e.g. research, others (Intended use for e.g. research, exchange, others) **Diagnostic features** (closely allied to/differ from), Central of development/derivation/origin (country/lab), citation of type/culture isolates.

Table 5/Column 1 add (Precautionary measures).

For B: Example 1 of Template for Article 18.2 (b)

Under Table 2/Column 1 add after phone **Official Mobile No** also

Under Table 4/Column 4 (Description) Add **Diagnostic features** under Living modified organisms. Precautionary measures are needed to be cited under this column.

For C: Example 2 of Template for Article 18.2 (b)

Under Table 1/Column 1 add after phone **Official Mobile No** also

Under Table 2 add **Affecting Environment** after Affecting Humans. Add **Liquid Nitrogen** after Dry Ice.

Under the self declaration (I hereby. …Governmental regulations). Add **Copy of Diagnostic description with center of origin (development/lab/country) and International/National Governmental regulations of exporting country/agency should be annexed.** The Annexure could be matched with the approved National regulations of importing country for acceptance.

For D: Blank example of Template for Article 18.2 (b)

Under Table 2/Column 1 add after phone **Official Mobile No.** also

Under Table 4/Column 4 add under after …events of transformation. **Lab or center where developed type/s preserved and database maintained.**

After Notifications to the BCH, add **computerized identification and safety tool kit/database.**

For E: Example 1 of Template for Article 18.2 (b)

Under Table 2/Column 1 add after phone **Official Mobile No** also

For declaration there is need for the conformity of both exporting and importing agencies.

For F: Example 2 of Template for Article 18.2 (b)

Under Table 2/Column 1 add after phone **Official Mobile No** also

Under Table 4/Column 4 under description add **Diagnostic features and center of origin/development** after Living modified organism.

JAPAN

[10 AUGUST 2004]
[SUBMISSION: ENGLISH]

1. Information of implementing the requirements of the first sentence of paragraph 2（a）of Article 18

Under the Article 28 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, which enforced 19th Feb. '04, and the Article 37 of the Regulations related to the Enforcement of the Law, Government of Japan has prohibited exporters to export LMOs for direct use for food, feed, or processing（FFP）to the Parties to the Cartagena Protocol on Biosafety without the indication stipulated in the Regulations.

In practice, exporters shall attach the following information along with the 13th form of the Regulations to the LMOs or its package/container or consignment invoice when exporters export LMOs for FFP:

1） "may contain" living modified organisms

2） and are not intended for intentional introduction into the environment.

3） The contact point for further information（name, address, and contact details（tel, telex or fax number, contact person）of the exporter and importer）.

Someone who violates the Article 28 of the Law and exported LMOs for FFP to the Parties of the Protocol without attaching necessary information or with false information shall be fined of no more than 500,000 yen.

2. Views of Japan regarding the detailed requirements referred to in the second sentence of paragraph 2（a）of Article 18, including specification of the identity of the LMOs for FFP

① Whether the extent of information should include taxonomic name, the gene modifications inserted and traits or gene changed

The necessary information for the document, which is referred in the second sentence of paragraph 2（a）of Article 18 of the Protocol, is required to make importing Parties to be able to identify the LMOs in order to assure that it does not have adverse effect on the conservation and sustainable use of biological diversity in the Parties. Therefore, the information shall include taxonomic name, the gene modifications inserted and traits or genes changed.

However, it is not always necessary to put the all above information itself on the document if the unique identification code is indicated, which makes the Parties to be able to access such information.

Japan recommends adopting the Unique Identifier of OECD as the unique identification since it is already in use.

② Threshold levels in the case of co-mingling of living modified organisms with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol

Japan is one of the importing Parties and does not accept any threshold level of unapproved LMOs since it is not clearly identified whether the LMOs would not affect adverse effect on the conservation and sustainable use of biological diversity of importing Parties. Therefore exporting Parties shall take appropriate emergency measures regulated in Article 17 of the Protocol when there is some high possibility that unapproved LMOs may be co-mingled in commodity for FFP.

Japan recognizes that there is a possibility to set certain threshold level for the unapproved LMOs in limited case when importing Parties evaluate the threshold levels in the case of co-mingling of the unapproved LMOs as to not affect adverse effect on the conservation and sustainable use of biological diversity in importing Parties. However the threshold level depends on the differences of transportation

condition and natural environment in each importing Party. Threshold level, therefore, must be set by each Party and Japan is negative to set any international standard for the threshold level.

As for the threshold level for approved LMOs, which already acknowledged that there is no possibility to affect adverse effect on the conservation and sustainable use of biological diversity of importing Parties, it must be determined by each party taking account of their own labeling requirements and consumer interests etc.., and it is not necessity to have international standard.

③ Implication of "may contain"

The Parties has to clarify the concept and appropriate standard for the words "may contain" as soon as possible.

Japan suggests that "may contain" is appropriate to use until detailed requirements indicated in the second sentence of paragraph 2（a）of Article 18 is clarified and in the case when each LMOs is not able to be identified（unintentional co-mingling of LMOs etc）. After the requirements by the second sentence of paragraph 2（a）of Article 18 are fixed in detail and each LMOs will be able to be identified, express as "contain LMOs（its name and so on）" would be appropriate.

Even for crops exported as non-LMOs for FFP, it is necessary to indicate as "may contain LMOs" if there is a possibility of unintentional co-mingling since it is impossible to identify such LMOs. Exporting Parties must supply the information of the LMOs which is possibly co-mingling in the crops through BCH. But document is not necessary when the degree of the co-mingling（which depends on method of separation of cultivation and handling, threshold level, etc.）meets the acceptable level for the importing Parties.

About the information of the LMOs which is highly possible to be co-mingled, it is necessary that importing Parties can confirm it through BCH. For the benefit of importing Parties to confirm the level of co-mingling of the LMOs in more detail, information on the BCH must be expanded to include commercial cultivation of the LMOs（area of cultivation, amount of production, share of production, export share of the crop, etc.）.

Standard of demarcation between segregation and non-segregation is different by each Party which based on the labeling system of importing Parties, production and handling situation of LMOs in exporting Parties and the necessary cost for segregation process. Therefore the standard of demarcation should not be determined on international bases but to be determined by each importing Parties under the Article 11 of the Protocol.

④ Unique identification

The information about LMOs for FFP on the document should make Parties to be able to confirm whether there is no possibility that the LMOs for FFP would have adverse effect on the conservation of biological diversity and sustainable use of it by importing Parties.

However due to the following points, it is not necessary to put all required information on the document but just put the unique identification code to assure the access to the necessary information:

1） Indicating the taxonomic name, the gene modifications inserted and traits or genes changed on the document would be too complicated procedure for the international grain trade.

2） Technical information is not always necessary for someone who does not have special knowledge on genetically modified organisms.

Unique identification should be simple and easy to use and internationally widely used. Considering these conditions, Japan recommends to adopt Unique Identifier of OECD as for unique identification.

In order to secure the importing Parties to be able to distinguish the LMOs whether it is approved or unapproved by exporting Parties and/or importing Parties, the information of the method to detect the LMOs should be added the information listed in the Annex 2 in the Protocol which is notified to the BCH. For this purpose, exporting Parties and exporters should make efforts to open the information and supply the sample that is necessary to detect the LMOs. On this behalf, exporting Parties and exporters of the LMOs should ensure the access to the necessary information through the unique identification used by importing Parties and importers.

To accomplish full role of unique identification, it is necessary to be made maximum effort to use BCH not only by Parties but also by non-Parties.

3. Experiences with the use of existing unique identification systems under the Protocol, such as Unique Identifier for Transgenic Plants of the Organization for Economic Co-operation and Development

Government of Japan has been directing the applicants of LMOs to give international unique identification, such as Unique Identifier of OECD, for LMOs which is prospected on market. Consequently the applicants of LMOs give UI of OECD for the LMOs when they apply.

Government of Japan has reported the UI to OECD when the government approved the LMOs.

Under the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, Government of Japan is continuously directing applicants to give UI of OECD when they apply for use of LMOs. Government of Japan will report the LMOs with UI to BCH, based on Article 11 of the Protocol, when the government approved the LMOs.

LIBERIA

[30 JUNE 2004]
[SUBMISSION: ENGLISH]

a) Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18.

VIEW. We have not had any experience relative to the above due to low capacity.

b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2(a) of Article 18, including specification of the identity of the living modified organisms (LMOs) that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs; and possible linkage of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification.

VIEW: We fully agree that taxonomic name, gene modifications inserted and traits or genes changed are necessary information as regards the detailed require of paragraph (22a) of Article 18 of the Protocol.

On the issue of the threshold levels in the case of co-mingling of LMOs and non- LMOS, 1% is acceptable in our view.

***Possible linkages of the issue with Article 17 of the protocol**: co-mingling of LMOs with non-LMOs is unintentional and unavailable at times considering large batches of seeds.*

It is very useful to develop a harmonized system of unique identification for traceability to engender effective risk assessment.

c) Information on experience with the use of existing unique identification systems under the Protocol, such as the Unique Identifier for Transgenic Plants of the Organization for Economic Cooperation and Development.

VIEW: We have no information on the use of any unique identification system as yet for risk assessment purposes.

LITHUANIA [29 JUNE 2004]
[SUBMISSION: ENGLISH]

In reply to you letter of 13 April 2004 we want to signify, that Republic of Lithuania has no any practical experience on handling, transporting, packaging and identification yet. When Lithuania became a full Member of European Union, the regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms; Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms and the other documents, which regulate the use of genetically modified organisms came into force immediate. And we have some law on regulation on handling, transporting, packaging and identification, but no practical experience.

MALI [1 JULY 2004]
[SUBMISSION: FRENCH]

Nous n'avons encore aucune expérience par rapport au point 7 de cette décision sur la manipulation, transport, emballage et identification des organismes vivants modifiés.

Notre exercice pour l'élaboration du cadre national de biosécurité continue en ce moment et aucune disposition n'est encore arrêtée concernant ces aspects. Il apparaît cependant clairement que **nous sommes favorables à des indications claires en ce qui concerne le paragraphe 2 de l'article 18 du Protocole**.

NB : Les réponses données dans ce document doivent être considérées comme une tentative de contribuer au processus et ne sont donc, par conséquent, pas exhaustives.

MAURITIUS [29 JUNE 2004]
[SUBMISSION: ENGLISH]

Please note that Mauritius has enacted its GMO legislation only last mid April, and has yet to promulgate the relevant Regulations of the GMO Act. We have therefore, so far, no experience in GMO/LMO dealings, for example in the implementation of the requirements of paragraph 2 (a) of Article 18 of the Cartagena Protocol (Handling, Transport, Packaging and Identification).

(a) We have no experience yet in the implementation of the above requirements. The Genetically Modified Organisms Act 2004, the first legislation in Mauritius pertaining to GMO's, has been enacted on 15 April 2004. Regulations to be made under the Act have still to be finalized and promulgated.

(b) We are agreeable to the submission of detailed requirements, including threshold levels, for LMO's handling, transport, packaging and identification.

The Mauritian GMO Act makes provision for detailed information to be given by the applicant wishing to deal in any activity related to LMO's (including import, export, production, release and distribution).

(c) We have no experience with the use of existing unique identification systems under the Protocol.

MEXICO [30 JUNE 2004]
[SUBMISSION: SPANISH]

(a) Información sobre la experiencia, si se tiene, en la implementación de los requerimientos de la primera frase del párrafo 2 (a) del artículo 18.

Sobre los organismos vivos modificados (OVM) destinados a uso directo como alimento humano o animal, o para procesamiento, y que no están destinados para su introducción intencional en el medio, México ha celebrado un arreglo trilateral con los gobiernos de Canadá y Estados Unidos de América ("Requisitos de documentación para organismos vivos modificados para alimentación, forraje o para procesamiento OVM/FFP"), el cual ha sido ya firmado por los tres países, al igual que el Plan de Trabajo del mismo arreglo ("Plan de Trabajo de la Iniciativa de Biotecnología de América del Norte (NABI) para el Intercambio de Información en el Marco del Arreglo Trilateral").
Este instrumento trilateral es también un ejemplo de la implementación, de los artículos 2 y 24.1 del Protocolo de Cartagena, que señalan que cada Parte tomará las medidas legislativas, *administrativas* o de cualquier otra naturaleza necesarias para la implementación del Protocolo (art. 2) y que los Estados Parte podrán celebrar arreglos con Estados no Parte (art. 24.1).
Cabe señalar que el arreglo trilateral así como su plan de trabajo, se encuentran ya en línea, tanto en la página de CIBIOGEM (www.cibiogem.gob.mx) como en el BCH.
El arreglo trilateral presenta las siguientes características:

Naturaleza del arreglo trilateral

- No es un acuerdo o tratado internacional, sino la instrumentación de un tratado (Protocolo de Cartagena).
- Es un instrumento signado por autoridades agropecuarias de 3 países, en el ámbito competencial de los 3 Ministerios/Secretarías de Estado correspondientes.

Alcances del arreglo trilateral

- Ni la normatividad de Canadá ni la de USA obliga a identificar o a segregar, o a informar si un producto "puede contener OVM".
- Se gana acceso a información que no era posible exigir ni a Canadá ni a Estados Unidos.
- Canadá y USA informarán a México, al exportarle un producto, si "puede contener OVM".
- Con el arreglo trilateral, México instrumenta prácticamente el artículo 18.2.a) del Protocolo de Cartagena.

Contenido del arreglo trilateral

- Tiene una vigencia de 2 años, congruente con el plazo en el cual se decidirá en el seno de la COP/MOP y del Protocolo de Cartagena, los requisitos de documentación a que se refiere el artículo 18.2.a).

- El arreglo trilateral no se refiere a etiquetado sino a identificación, es decir, a información que se anexa en los pedimentos de importación/exportación.
- En la factura comercial, en los casos en que proceda este señalamiento conforme al arreglo, aparecerá la leyenda "Este embarque puede contener organismos vivos modificados para uso directo como alimento humano o animal o para su procesamiento y que no están destinados para su introducción intencional en el medio".
- La leyenda de que "puede contener…" será utilizada para *commodities* destinados a alimento humano o animal o para su procesamiento, debiendo estar el OVM de ese *commodity* autorizado por el país de exportación.
- Excepción: a) Embarques de productos donde el país de exportación no tenga en comercio ningún OVM de esa especie; b) Cuando el importador y exportador hayan definido un cargamento sin OVM, en su caso, y en el cual se detecte una presencia de hasta 5% de contenido transgénico, siempre que esta definición no entre en conflicto con la normatividad del importador.
- La presencia accidental de OVM no es justificante para utilizar la leyenda "puede contener…".
- A través del arreglo se mantendrá un intercambio de información científica.
- El arreglo trilateral no afecta el derecho de importar un OVM bajo la regulación nacional o de conformidad con una evaluación del riesgo de acuerdo al artículo 11 del Protocolo.
- Las partes del arreglo pueden modificarlo o actualizarlo cuando sea necesario.
- El arreglo trilateral cuenta con un plan de trabajo, que contiene elementos pormenorizados de información (*ver* inciso b)

En relación a la presencia no intencional (adventicia) establecida en el arreglo trilateral, del 5%, México podría adoptar umbrales diferenciados, por ejemplo, para especies en los cuales nuestro país es centro de origen y diversidad genética, donde el umbral fuera más alto que para otras especies y esta sería otra medida para reducir los riesgos de una liberación no intencional.

El Gobierno de México ha aceptado el umbral de 5%, sujeto a revisiones en función del desarrollo de su capacidad técnica.

(b) Puntos de vista sobre los requerimientos detallados referidos en la segunda frase del párrafo 2 (a) del artículo 18, incluyendo la especificación de la identidad de los OVM destinados para uso directo como alimento, pienso o procesamiento (si la información debe incluir nombre taxonómico, las modificaciones insertadas a genes y rasgos o genes cambiados); niveles de riesgo en caso de mezcla de OVM con no-OVM; y posibles vínculos con el tema del artículo 17 del Protocolo; el lenguaje "puede contener" y cualquier identificador único.

En el plan de trabajo del arreglo trilateral, a que se hace referencia en el inciso (a), se señalan ciertos elementos que se deberían considerar al instrumentar el Protocolo de Cartagena, y que se transcriben a continuación:

2. Los países buscarán desarrollar mecanismos para el intercambio de información respecto a la biotecnología y Bioseguridad en agricultura, incluyendo:

2.1. Proporcionar vínculos para los desarrolladores quienes podrían voluntariamente identificar eventos aprobados pero no comercializados;

2.2. Proveer información, conforme la misma esté disponible, sobre eventos de transformación liberalizados en el medio ambiente y las superficies plantadas y cosechadas;

2.3. Impulsar enfoques conjuntos con los desarrolladores, por ejemplo, la presentación para evaluación;

2.4. Trabajar en el desarrollo de acuerdos sobre criterios comunes de evaluación de riesgos;

2.5. Intercambio de información sobre aspectos científicos e información sobre investigación en evaluación de riesgos en cada país, así como en investigación sobre el impacto de la biotecnología en cada país;
2.6. Intercambio de información respecto a evaluaciones, verificación de procesos y metodologías de detección;
2.7. Identificar oportunidades y prioridades con respecto a la capacitación y desarrollo de capacidades; y
2.8. Aspectos de cumplimiento de las regulaciones:
2.8.1. hacer expedito el proceso de intercambio de información técnica; y
2.8.2. desarrollar mecanismos de coordinación sobre rastreabilidad y acciones regulatorias.

Fuera de estos elementos, no se han analizado en la CIBIOGEM los demás requisitos sugeridos en el actual inciso o en la segunda frase del artículo 18.2.a).

(c) Información sobre la experiencia con el uso de sistemas de identificación único existentes bajo el protocolo, tales como el identificador único para plantas transgénicas de la OECD.

Por lo que respecta al identificador único, la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA), cuyo Titular forma parte de la CIBIOGEM, se encuentra en proceso de implementación de un sistema de identificador único, tomando como base la propuesta de la OECD.

Esta implementación se da, principalmente, en el ámbito de las solicitudes presentadas ante esta Secretaría, que se refieren a la siembra experimental de OGM.

NORWAY [23 AUGUST 2004]
[SUBMISSION: ENGLISH]

Decision BS-I/6 of the First Meeting of the Parties (MOP1) to the Cartagena Protocol, requests Parties to provide views on Article 18(2)(a) to the Executive Secretary by 30 June 2004.

Norway has already submitted views on detailed requirements for labelling and identification of all three categories of living modified organisms (LMOs) in a submission to the Secretariat of 14 October 2003. Please find a copy of this submission enclosed.

The following information is requested in notification No. 2004-027 of 13 April 2004:

(a) ***Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2 (a) of Article 18***

Norway is of the view that the first and second sentence of Article 18(2)(a) are closely linked to each other and have to be dealt with together. MOP1 confirmed this by adopting requirements which clarify the whole of Article 18(2)(a).

Norway is in the process of developing a regulation on transport, imports and exports on GMOs to our Gene Technology Act which will also address the issue of documentation requirements for LMOs for food, feed or processing covered by Article 18(2)(a). The new transport, export and import regulation on GMOs will also contain requirements for documentation of GMOs in accordance with the Cartagena Protocol on Biosafety and MOP1 Decision BS-I/6. The aim is that the regulation should enter into force 1 January 2005.

When products are defined as feed or food products in the Norwegian Act on Food Production and Food Safety, the Act gives the legal basis for labelling of such products. The detailed labelling requirements

can be found in regulations, namely for feed in the Regulation on feedingstuffs, and for food and food products in the Regulation on food and food products.

According to these regulations feed, food or foodstuffs containing GMOs shall be labelled "This product contains genetically modified organisms". Feed and food products consisting of GMOs or which are produced from more than 2 % GMOs shall be labelled as "This product contains genetically modified organisms" or "This product is produced from GMOs".

Pursuant to Section 15 of the Gene Technology Act, labelling is one of the conditions for approval of GMO. The GMOs that are approved in Norway are also approved in the EC, and the requirements on labelling in those approvals are also applicable in Norway. The labelling requirements in the new EU Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed Regulation (EC) No1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms and amending Directive 2001/18/EC are being considered for incorporation in the EEA agreement (the Agreement on the European Economic Area) and would consequently be applicable to Norway.

The text of these Regulations is available on the Protocol's Biosafety Clearing House.

(b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18, including specification of the identity of the LMOs that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification

MOP1 adopted Decision BS-I/6 which elaborated the existing requirements under Article 18(2)(a) of the Protocol. Shipments of LMOFFPs are to be accompanied by a commercial invoice or other documents to specify that the shipment "may contain" LMOs and is not intended for introduction into the environment. A contact point (the importer, exporter or any appropriate authority) should also be included. In addition, the decision 'urges' Parties and other governments to require information on:

-the name of the organism;

-the transformation event;

-the unique identifier code.

Moreover, the decision encourages Parties to require that exporters specify, in documents accompanying transboundary movements 'known to intentionally contain LMOFFPs', that the shipment contains LMOFFPs, the identity of the LMO, and any unique identification, where possible. Finally, the decision invites Parties to apply the OECD Unique Identifiers for Transgenic Plants to living modified plants. Therefore, Decision BS-I/6 provides concrete ways of implementing Article 18(2)(a). Norway supports the decision and believes that it should be strengthened, with a view to adopting detailed requirements within two years from the entry into force of the Biosafety Protocol (i.e. at MOP2) as required by Article 18(2)(a). This would allow importing countries to verify that imported LMOs for food, feed or processing are those that they agree to import. Norway prefers the adoption of a stand-alone document to accompany LMOs that are intended for food, feed or for processing. The documentation requirements to be included in transport documents can be found in the Norwegian submission of 14 October 2003 which is enclosed.

With regard to point 2 above on thresholds in case of co-mingling with non-GMOs, Norway believes that the issue of thresholds should be addressed under Article 18(2)(a) of the Protocol. Under the EC regulations, the traceability and labelling requirements of LMOs intended for direct use as food, feed or

for processing do not apply to trace amount of authorised GMOs no higher than a threshold of 0.9%, provided that these traces are adventitious or technically unavoidable. The EU has also adopted a specific threshold of 0.5% for GMOs which have not been authorised according to EU rules but have already been positively risk assessed. As mentioned earlier, these EU regulations are being considered for incorporation into the EEA Agreement.

Finally, with regard to linkages with Article 17, Norway considers that the scope of Article 17 covers all LMOs likely to have significant adverse effects on the conservation and sustainable use of biodiversity taking into account risks to human health in affected or potentially affected States.

c) Their experiences with the use of existing unique identification systems under the Protocol, such as the OECD Unique Identifier for Transgenic Plants;"

The OECD Unique identifier for Transgenic Plants is used in new applications on placing on the market of GMOs within the EU and EEA (European Economic Area).

SUBMISSION FROM NORWAY - EXAMPLE OF TEMPLATE FOR ARTICLE 18.2 (A) OF THE CARTAGENA PROTOCOL

Date:

Transport documentation of LMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (a) – LMOs intended for direct use as food, feed or processing only

	Exporter	Importer	Contact point
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Unique identification number in BCH:

Description of the LMO(s), including specification of their identity:

Ordinary name of the LMO(s) (including variety and transformation event for all LMOs in the shipment if relevant)	
Taxonomic name	
Gene modification (characteristics, including inserted or changed traits and genes)	

Requirements by importing country:

Reference to import approval	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement.

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	**Amount**	**Weight / Volume**	**Value**

I declare that the information above and this shipment of LMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:_____

SUBMISSION FROM NORWAY - EXAMPLE OF TEMPLATE FOR ARTICLE 18.2 (B) OF THE CARTAGENA PROTOCOL

Date:

Transport documentation of LMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (b) – LMOs destined for contained use only

	Exporter	Importer	Contact point
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Ordinary name of the LMO	
Taxonomic name	
Unique identification number, if existing	
Reference to BCH, if relevant	
Risk categorization, if relevant	
Type of intended use: Commercial Research Other	

If required by importing country:

Reference to import approval	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement.

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	Amount	Weight / Volume	Value

I declare that the information above and this shipment of LMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:___

ROMANIA

[5 JULY 2004]
[SUBMISSION: ENGLISH]

In Romania is in force *the Law no 214/2002 for the approval of the Government Ordinance No 49/2000 on obtaining, testing, use and commercialization of Genetically Modified Organisms resulting from modern biotechnology as well as the products thereof*, which transposes the specific EU legislation (Directive 90/219/EEC, amended by Directive 98/81/EC and Directive 2001/18/EC, repealing Directive 90/220/EEC) and is consistent with the objective of the *Cartagena Protocol on Biosafety, ratified by the Law no 59/2003.*

The legislative framework will be developed according to the Romanian engagements in the Position Paper- Cap.22. Environment. During 2005 and 2006 years (as established date of accession in the EU is January 2007), Romania has to transpose and implement the last EU legislation regarding genetically modified organisms:

- **Regulation (EC) No 1946/2003** of the European Parliament and of the Council on transboundary movements of genetically modified organisms;
- **Regulation (EC) No 1830/2003** of the European Parliament and of the Council concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;
- **Regulation (EC) No 1829/2003** of the European Parliament and of the Council on genetically modified food and feed;

In the present, according to Art. 35 of the Law no 214/2002, **importers (including importers of living modified organisms intended for direct use as food or feed, or for processing), are obliged to notify in written the Ministry of Environment and Water Management (MEWM), as national competent authority, before making any import with LMOs or products thereof.** Notification is according to the Annex 11 of the Law.

The Law provides, too, the procedure of the Advance Informed Agreement prior to the first transboundary movement for introduction on the market of a LMO or a combination of LMOs.

Until now, no notification has been received by the MEWM for the imports of LMOs, intended for direct use as food or feed, or for processing (genetically modified grains, for example).

MEWM has received Notifications only for the import of genetically modified higher plants (seeds), for their deliberate release into the environment and placing on the market. (For example, Notifications for approving imports of Soya Roundup Ready GTS 40-32 seeds; these are indicating the OECD Code).

Romania is now implementing the UNEP-GEF Project "Development of the National Biosafety Framework" and the Ministry of Environment and Water Management acts as the National Executing Agency.

They will be identified gaps in the actual legislation and will be made recommendations for developing the actual regulatory framework by implementing the provisions of the Cartagena Protocol on Biosafety.

1.2. Point of view regarding the further activity of the open-ended technical expert group for establishing detailed requirements for imports of LMOs intended for direct use as food or feed, or for processing:

- To be established, for the importers (or exporters, as is the case) of LMOs, the obligations:

- To specify, in the documentation accompanying transboundary movements known to intentionally contain LMOs, that the shipment may contain LMOs that are intended for direct use as food or feed, or for processing and is not intended for intentional release into the environment; Or

  The shipment to be accompanied by a document from an accredited LMOs laboratory, specifying the presence of the LMO or the content in the LMO (accordingly to the requirements of the legislation in force in the importing country);
- To specify the name (commercial and scientific) and identity of the living modified organism and an unique identification number- OECD code, placed under the Biosafety Clearing House, or a special Custom Code, for each genetically modified commodity (For example, in the present there is only one Custom Code for both, genetically modified seeds, and genetically modified grains, according to the EU legislation);
- To describe the methods for the safe handling, storage, transport, use, packaging, labeling and intervention in the case of emergency;
- To present details regarding the origin country of export, the last exporter, the importer and the contact point for the case of emergency;
- To declare that the transboundary movement of LMOs is according to the Cartagena Protocol on Biosafety;
- To present, at the Customs, the approval for the import, from the national competent authority in the country of import, according to its National legislation, or details about the bilateral or multilateral accord, which regulates the import.
  - To establish a model for the accompanying documentation, consistent with the international standardized documentation system, compulsory for all the Parties or non-Parties to the Protocol, involved in the transboundary movement of LMOs for direct use as food or feed, or for processing.

Related to the point 1.2, we consider as being necessary to be accomplished the following:

- To be developed and assigned an unique identifier (or to be established a special Custom Code) for each approved transgenic material which is subject to a transboundary movement and a register for the unique identification codes, under the Biosafety Clearing House;
- All the involved countries, to actively participate in the Biosafety Clearing House Mechanism;
- To be developed sampling and detection, identification and quantification techniques for LMOs and derived products, covering seeds, grains, food and feed.

SAINT LUCIA [20 JULY 2004]
[SUBMISSION: ENGLISH]

The detailed requirements referred to in the second sentence of paragraph 2 should include taxonomic name, the gene modifications inserted, traits or genes changed; threshold levels in the case of comingling of LMOs with non-LMOs; any information on the possible adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health, as well as available information about possible risk management measures; and a point of contact for further information. The "may contain“ language should be included and any unique identification.

SRI LANKA [9 JULY 2004]
[SUBMISSION: ENGLISH]

(a) Information on experience in the implementation of the requirements of the first sentence of paragraph 2 (a) of Article 18: Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment, as well as contact point for further information.

As a precautionary measure, Sri Lanka decided to impose restriction on importation of Genetically Modified Foods and some food products that were imported. The restrictions were to be revised when the safety of these foods are known. The ban was on import of six Genetically Modified Foods and some food products containing these as ingredients, as safety for human consumption was not known and the safety evaluation procedures were not in place.

The Food Advisory Committee of the Ministry of Health formulated the regulations under the Food Act and the regulations were cited as Food (Genetically Modified Foods) Regulations – 2001. The food ban prohibited import, manufacture for commercial purposes, transport, store, distribute, sell, offer for sale any food raw or processed or any ingredient of food, food additive that has been subjected to any genetic modification using DNA recombinant technology, or any food that contains one or more ingredient, preservative or additive that have been subjected to genetic modification. Importation of any food belonging to the specified schedule of the regulations should be certified from the competent government authority or an accredited laboratory of the exporting country that the food product does not contain any material or ingredient that has been subjected to genetic modification. The schedule I included 21 food items, mainly 6 derivatives/products of Soya, Corn/ Maize, Tomato, cheese, potato, yeast, beet sugar and microbiological starter cultures used in foods.

The Food Regulations 2001 could not be imposed in compliance with WTO agreements, where Sri Lanka is a signatory. Regulations was indefinitely suspended from coming into operation.

However, a panel of experts is working on regulations, for a labeling process instead of the proposed ban, thus the consumers have their choice in what they consume. In Sri Lanka there are no laws stipulating labeling is a mandatory requirement. But under the National Biosafety Framework Development Project a policy and a legal framework is being prepared. This considers aspects of mandatory labeling of genetically modified organisms and products. Standards should be developed for labeling.

(b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18:

The information on the accompanying documentation of GMOs should include:

1. Regarding identity of genetically modified organisms, it should be clearly identified as genetically modified organisms or contains genetically modified organisms; as living modified organisms for direct use as food or feed, or for processing. Identification as "may contain" cannot be accepted.

2. Details of molecular biology of GMOs:

Brief description on organisms that have been modified, molecular characterization of the genetic modification including description of the characteristics of the inserted gene, significant changes or unintended effects on the composition, etc.

3. Toxicity and allergenicity implications of GMOs and handling procedures for allergenic substances

4. Any unique identification

5. Details of a contact point for further information; the exporter/importer/shipping line

6. Any requirements for safe handling, storage and transport

c) Information on experience with use of existing unique identification systems under the protocol.

At present, no experience.

SWITZERLAND [28 JULY 2004]
[SUBMISSION: ENGLISH]

a) Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2 a of Article 18.

On this issue, we would like to refer to our position already expressed in document UNEP/CBD/ICCP/3/INF/5.

According to our national requirements, documentation accompanying transboundary movement of living modified organisms that are intended for direct use as food or feed or for processing (LMO-FFP) to Switzerland should be clearly identified as containing LMOs. The second element required by article 18.2a in the documentation (i.e. "not intended for intentional introduction into the environment") is also requested by the Swiss authorities for such material.

b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2(a) of Article 18, including specification of the identity of the living modified organisms (LMOs) that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs; and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification;

Detailed requirements:

The detailed requirements for documentation accompanying the transboundary movement of living modified organisms that are intended for direct use as food or feed or for processing (LMO-FFP) should basically be the same as those listed in paragraph 2 (c) of Article 18 for documentation accompanying the transboundary movement of LMOs that are intended for intentional introduction in the environment.

In other words the documentation accompanying the transboundary movement of LMO-FFPs shall contain the following information:

- A clear identification that the shipment contain living modified organisms;
- An internationally recognized unique identifier code such as the OECD unique identifier. In the absence of such a unique identifier, the identity (common, scientific and where available commercial name) as well as the relevant traits and characteristics of the LMO (including event of transformation) shall be specified;
- Any requirements for the safe handling, storage, transport and use:
- The contact point for further information;
- The name and address of the consignee;
- A declaration indicating that the LMOs are not intended for intentional introduction into the environment.

Threshold level

In Switzerland, threshold level for labelling is currently 1% for food products, respectively 3% for feed products containing living modified organisms.

Proposals to amend the regulatory provisions adressing food and feed deriving from living modified organisms are currently under discussion. The aim is to implement the new Federal law relating to non human gene technology (Gene Technology law) which entered into force January 1, 2004.

Other issues

We are of the opinion that the reference made in the Secretariats' notification to a possible linkage between article 18 and article 17 of the Cartagena Protocol is not appropriate since this question is not mentioned in the terms of reference for the open-ended technical expert group on identification requirements of LMO-FFP adopted by COP-MOP 1. There is no direct linkage between those two articles since article 18 addresses the issue of handling, transport, packaging and identification associated with intentional transboundary movement of living modified organisms.

c) Information on experience with the use of existing unique identification system under the Protocol such as the Unique identification system of the OECD.

We are in the process of introducing requirements for existing unique identification system such as the unique identification system of the OECD in the documentation for LMOs intended for commercialisation. This will apply to domestic documentation as well as documentation accompanying the transboundary movement.

TOGO [30 JUNE 2004]
[SUBMISSION: FRENCH]

Conformément à la décision BS-I/6 de la première reunion de la conférence des Parties servant comme réunion des Parties au Protocole de Cartagena sur la Biosécurité (COP-MOP), laquelle demandait aux Parties et autres gouvernements et organisations internationales de fournir des informations concernant le paragraphe 2(a) de l'article 18, j'ai l'honneur de vous signaler que dans le cadre du Projet "Cadre National de Biosécurité", en cours d'exécution, le Togo se propose d'adopter un système d'identification unique des organismes vivants modifiés (OVM).

Cependant, en l'état actuel des études réalisées, nous ne disposons ni de laboratoire d'analyse ou d'équipements appropriés pour identifier les OVM, ni de dispositions juridiques habilitant des structures à procéder à des contrôles et à des identifications d'OVM sur le territoire Togolais.

L'adoption du Cadre National de Biosécurité et sa mise en oeuvre effective devraient permettre au pays de disposer des institutions et outils appropriés pour l'identification des OVM destinés à l'alimentation humaine et animale au Togo.

UGANDA [28 JUNE 2004]
[SUBMISSION: ENGLISH]

a) Uganda has no experience in implementation of Para. 2(a) of Article 18. This is because our legislation on LMOs is not yet completed and as such there is no importation of LMOs pending completion of the national legislation.

b) Views regarding detailed requirements referred to in the second sentence of article 18.2 (a) should include:
   i) The common name of the LMO
   ii) The scientific name of the LMO
   iii) The unique identifier code where available
   iv) The trade name where available
   v) The transformation event of the LMO
   vi) The point of contact for further information
   vii) The developer of the LMO
   viii) The exporter
   ix) The importer/consignee
   x) Any requirements for safe handling, storage and use

c) Uganda has no experience with use of unique identifiers.

UNITED STATES OF AMERICA [30 JUNE 2004]
[SUBMISSION: ENGLISH]

Despite the importance of Article 18.2(a) to the function of the Protocol, the first Meeting of the Parties (MOP-1) failed to provide clear guidance on how Parties should implement this Article in a practical manner without unnecessarily disrupting commodity trade. The different procedures set out under the Protocol for LMOs intended for environmental release and LMOs intended for food, feed, or for processing (LMO-FFPs) reflect the understanding that LMO-FFPs pose a substantially lower potential risk to the environment or biodiversity than LMOs intended for environmental release. The original intent of including a separate provision for bulk commodity shipments was to ensure continued movement of global trade whether for commercial or humanitarian purposes. The MOP decision(s) on Article 18.2(a) undercut that intention.

A. Experience in the Implementation of the Requirements of the First Sentence of Article 18.2(a)

The first sentence of Article 18.2(a) states that LMO/FFPs should be accompanied by documentation that clearly identifies that the shipment "may contain" living modified organisms that are not intended for intentional introduction into the environment. The Protocol does not provide strong direction in this regard, and consensus has not been reached on when this documentation will be required – that is, what constitutes a LMO shipment.

In the absence of clear guidance regarding implementation of Article 18.2(a), the United States, Mexico, and Canada developed a trilateral arrangement in 2003 consistent with Articles 14 and 24 and the Protocol's objectives and also compatible with current commercial trade practices. The arrangement clearly articulates which commodity shipments are subject to the "may contain" language; what the language should say; and where it should appear. Using this approach, officials in the country of import receive clear notification that a shipment may have LMO content, but that it is intended for direct use for food, feed or processing.

The arrangement consists of mutually agreed upon key elements that clarify the documentation requirements of Article 18.2(a) unless and until a future COP/MOP decision provides more specific guidance. It articulates a practical definition for LMO and non-LMO shipments for food, feed, or for processing for purposes of applying the "may contain" documentation requirement, but would not supercede the domestic regulations of any importing country, should they exist. It does not sanction transboundary movements of unapproved products.

We note that the International Grain Trade Coalition has issued a Notice to Trade that incorporates the key concepts of the trilateral arrangement and recommends that exporters and importers use this approach to avoid confusion and promote consistency in international commodity trade.

The United States recommends that Parties implement Article 18.2(a) in accordance with the elements in the trilateral arrangement. A copy of the trilateral arrangement and an example of a commercial invoice (with proprietary information deleted), showing how the arrangement is implemented, are attached to this document as attachments A and B.

B. Views Regarding the Detailed Requirements Referred to in the Second Sentence of Paragraph 2(a) of Article 18

The United States believes that the key elements of the U.S./Canada/Mexico trilateral arrangement are consistent with Article 18.2(a) of the Protocol (first and second sentences). We urge Parties to consider the practical implications for both importers and exporters and for government officials of imposing additional detailed identification requirements for LMO-FFP shipments, and whether providing this information on the shipping documentation adds value beyond required information provided on the Biosafety Clearinghouse.

Specification of the Identity of the LMOs: Requiring additional or more complex documentation, such as a list of specific LMOs or additional detail about the genetic modifications, goes beyond the intended purpose of this Article. The "may contain" language serves to *inform* authorities in the country of import that LMO varieties may be included in the shipment. Such notification provides importers with information that may enable them to meet domestic requirements for handling, shipping or use. The "may contain" language is not designed to be a tool for risk assessments, or a basis for a decision to allow importation. The documentation accompanying commodity shipments is designed to provide importers with the information they need to comply with their governments' regulations for the safe handling of these products, not whether the import of a specific product is legally permitted. Decisions on importation of specific products should be taken before the product is exported from the country of origin. If there are further questions about what may be present in a shipment, the Biosafety Clearinghouse is a useful resource in this regard.

Threshold Levels in the Case of Co-Mingling of LMOs with Non-LMOs: The topic of thresholds is complex due to testing limitations and the nature of bulk grain production, handling, and transportation systems - where commodities with similar qualities are freely commingled. These systems cannot guarantee that shipments of non-LMO commodities will not contain small amounts of other materials possibly including LMOs. Considering that the "may contain" language is intended to inform authorities in the country of import, but is not intended to be the basis of regulatory decisions on the importation of specific products, the United States supports the following approach for applying the "may contain" language:

1. For general commodity shipments presumed to contain LMO's (because LMO varieties of this crop are widely grown in the country of export– for example, U.S. corn and soybeans): *The "may contain" documentation APPLIES.* Information on these varieties, including decision documents, will be available on the Biosafety Clearinghouse.

2. For commodities where no LMO varieties are authorized in or sold from the country of export: *The "may contain" documentation DOES NOT APPLY.*

3. For small-volume, high-value, specialty-type shipments of non-LMO commodities that have LMOs in general "parallel" commerce; for example, organic, food-grade soybeans, or a shipment of non-LMO U.S. corn, when the exporter and importer have contractually defined a non-LMO shipment (that is, a marketing definition): *The "may contain" documentation DOES NOT APPLY.*

While this category of commodities is relatively low-volume and shipped to a limited number of markets, we believe it is appropriate to add the following conditions to this exception to the "may contain" documentation requirement:

- such shipments must achieve a minimum of 95 percent non-LMO content, and
- the buyer/seller definition cannot conflict with regulations of the importing country

The 95 percent minimum is not derived through scientific process and has no biosafety regulatory implications. We included a minimum number to prevent a buyer and seller from developing a definition that clearly would be disingenuous and not in line with the spirit and intent of the Protocol; for example, calling a 25/75 percent mixture of LMO/non-LMO's a "non-LMO shipment." This marketing definition is consistent with current commercial practices.

4. Adventitious presence (LMOs in a non-LMO shipment) should NOT be a trigger for the "may contain" documentation.

Possible Linkages of the Issue with Article 17 of the Protocol; the "may contain" Language, and any unique identification: The United States does not believe that Article 17 can be linked to matters regarding the "may contain" language. While Article 18.2(a) relates to identifying cargoes that "may contain" LMO/FFPs (in compliance with any relevant decisions on importation that have been taken by the importing country), Article 17 addresses *unintentional* transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. As such, these two provisions of the Protocol are mutually exclusive.

C. Experiences with the Use of Existing Unique Identification Systems

The United States has actively participated in the Organization for Economic Cooperation and Development's (OECD) work to develop a unique identification system for transgenic plants. We have also been working for over three years, along with many other countries, to develop mechanisms to provide regulatory and scientific information on LMOs to the Biosafety Clearinghouse (BCH) Article 11.1 database on LMO FFPs.

The OECD unique identifier (UID) system for transgenic plants is a useful regulatory tool for access to information within databases on a specific product. The use of the unique identifier promotes international regulatory consistency by ensuring that regulators and decision makers can distinguish identical products that may have been reviewed under different names. The use of the UID alleviates any potential for confusion by regulators as to the exact nature of the product being reviewed and makes the possibility of retrieving information developed by other regulators feasible.

The experience of the United States is that the OECD UID system for plants can be successfully implemented. We have received from the applicants UIDs for many LMO plant products that have completed the U.S. regulatory review process. The United States has found the OECD UID to be a practical tool for accessing information from a database regarding a particular product. However, early experience with the UID system has highlighted some issues that still need to be resolved. For example, UIDs are not always available for products that were reviewed a number of years ago, and original applicants may no longer be in business or may be under new ownership. Another emerging issue that needs to be resolved is how to handle products containing stacked events. The United States believes that the OECD guidance shows adequate flexibility and should be followed while experience on the issue accumulates. In all cases, we believe that the country in which the events or products are first reviewed should retain sole responsibility for determining what unique identifier the developer or applicant has assigned to new LMO plants and reporting this UID to the relevant database(s).

The United States is also participating in discussions on UIDs for micro-organisms within the OECD. We are concerned that the same system of event designation that was developed for plants might not be

appropriate for microbes. Highly sophisticated systems for identification of certain microbes and microbial products already exist and are internationally agreed upon and these systems may suffice for accessing information within databases. We note that currently very few genetically engineered bacterial micro-organisms intended for use in the environment seem to be available for commercial use or international trade Similarly, there are existing mechanisms to provide unique identification for animals that may be useful as UIDs for access to information within the BCH. We support the OECD as an appropriate forum for discussion of using existing (harmonized) systems of identification of other organisms such as micro-organisms, animals, etc. as regulatory tools to provide access to information that will be posted to the BCH.

Unique Identifiers and the BCH: The United States has been very supportive of the development of the BCH as it provides an increased level of transparency internationally and provides access to science-based information regarding product reviews and risk assessment of bioengineered crop plants. The UID is a useful tool with regard to accessing information about a particular product on the Article 11.1 database. The unique identification field allows regulators and other officials to assure they are accessing information regarding a specific product.

While the United States believes the unique identifier system is a valuable tool for regulatory consistency, some issues have arisen during the early phases of implementation of the BCH with respect to UIDs that will require further consideration and resolution. For example, as mentioned above, there are particular products that have been approved that have not been assigned unique identifiers as per the OECD system. This is a particular problem for products that were reviewed a number of years ago. Our experience has been that countries have been able to find these products on the U.S. domestic website and database, but have had difficulty finding these products on the BCH. Therefore, we believe that it would also be useful to have these databases searchable for the transformation event or other identifying number to alleviate this situation. If a UID is not available, it may be appropriate to designate the transformation event identification as a UID, although there will need to be further discussions in the OECD as to who would be responsible for making these assignments for products not given a UID by the developer or applicant.

We also have some recommendations to improve the operability of the BCH. For countries and applicants to assure that a particular alphanumeric number is not already in use, we recommend that the registry of UIDs in the menu to the left of the database only be a list of the unique identifiers. It should also be designated as the registry as it currently is not. The registry should be separate from the Article 11.1 database itself and not linked to other information (or any information that is not from the BCH database). Such a listing would allow officials to check whether a particular unique identifier has already been assigned. Secondly, there should be a way to list ‘all’ unique identification within the field in the Article 11.1 database and one should be able to link from this field to the data and information about the associated product within the database.

We also note that the BCH databases contain information on all products for which countries have completed reviews and allow marketing, including those that were never commercialized or that were once commercialized but no longer are. We recommend that there be continuing discussions on this issue

Attachment A

Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing (LMO/FFP's)

The purpose of this document is to articulate an understanding among the United States, Canada, and Mexico, hereinafter also referred to as the "Participants," with respect to the documentation requirements of the Cartagena Protocol on Biosafety (CPB) pertaining to living modified organisms intended for direct use as food or feed, or for processing (LMO/FFP's). Specifically, the objective of this arrangement is to clarify documentation requirements such that they fulfill the objectives of the CPB without unnecessarily disrupting commodity trade.

The United States and Canada are not Parties to the CPB at this time. However, Article 24 states that transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objectives of the CPB, and that Parties and non-Parties may enter into arrangements, such as this, regarding such transboundary movements. This arrangement also meets the requirements in Article 14 of the CPB to accommodate the eventuality of either the United States or Canada becoming a Party to the CPB.

Article 18.2(a) of the CPB states:

> "Each Party shall take measures to require that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information.
>
> "The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol."

Article 18.2(a) of the CPB will be implemented as follows:

1. The "may contain" language, when included as per section 4 below, should appear on the commercial invoice as provided by the exporter. The importer is responsible for receiving the invoice and maintaining it after entry.

2. The "may contain" language, when included, should state:

> "Cartagena Biosafety Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

[page 2 of 3]

3. The last exporter prior to the transboundary movement and the first importer after the transboundary movement are to be named on the invoice and are the contact points for further information.

4. Applicability:

   a. The "may contain" documentation will be used for all transboundary movements of commodities intended for food or feed, or for processing, where an LMO of that commodity species is authorized[1] in, or sold from, a country of export, except:

      (i) Shipments for which the exporting country does not have in commerce any LMO of that species; or
      (ii) When the exporter and importer have contractually defined a "non-LMO shipment;" provided, that such a shipment achieves a minimum of 95 percent non-LMO content, and that such definition does not conflict with regulations of the importing country.

   b. Adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation.

Mexico (as a Party), Canada and the United States (currently as non-Parties) affirm that exporters and importers trading commodities with documentation according to these provisions have fulfilled both the objectives and the current requirements of Article 18.2(a) of the CPB.

The Participants hereby intend to maintain a continuous exchange of scientific information and to address issues on agricultural biotechnology that may arise among the three nations utilizing the expertise of scientific personnel. The Participants will elaborate on the subjects and mechanisms for information exchange.

This arrangement does not affect a Participant's decision on the import of LMO/FFPs under its domestic regulatory framework or according to a risk assessment, pursuant to Article 11 of the CPB.

Whenever in the judgment of a Participant issues of concern arise that would require further consultation on the interpretation or implementation of this document, including relevant decisions of the Meeting of Parties to the CPB, the Participants may jointly decide to make the necessary modifications and/or updates.

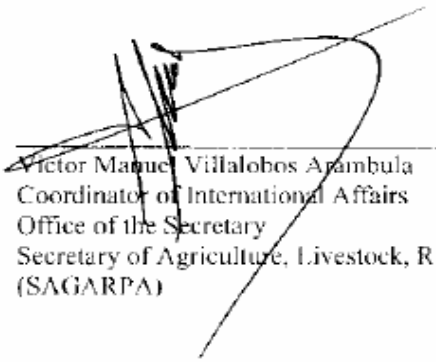
---

[1] Approved for unconfined release (Canada), deregulated (United States), or approved (Mexico), noting that the Biosafety Clearing House is an important reference tool.

[page 3 of 3]

This document will have effect for a period of two years, starting at the date of its signature. It can remain in effect beyond two years with mutual consent of all Participants.

Participant Signatures:

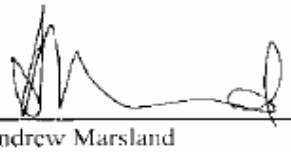


Date: October 29, 2003

Victor Manuel Villalobos Arambula
Coordinator of International Affairs
Office of the Secretary
Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food Mexico (SAGARPA)

Date: october 23, 2003

J.B. Penn
Under Secretary
Farm and Foreign Agricultural Services
U.S. Department of Agriculture



Date: October 28, 2003

Andrew Marsland
Assistant Deputy Minister
Market and Industry Services Branch
Agriculture and Agri-Food Canada

Attachment B

Commercial Invoice

Invoice Number: [redacted]
Date: 02-Jan-2004

Vessel:
M/V TRIUMPH

Loaded At:
[redacted], Louisiana

Bill of Lading Date:
02-Jan-2004

For:
VERACRUZ, MEXICO

Pack/Stowed:
In Bulk

Insurance For:
Sellers Account

Sale Date:
03-Dec-2003

Contract: [redacted]

Grade:
U.S. NO. 2 OR BETTER YELLOW SOYBEANS

% of Dockage: [redacted]

Covering: U.S. NO. 2 OR BETTER YELLOW SOYBEANS

Shipped Quantity: [redacted] Metric Tons

At CIF Price: U.S. [redacted] per Metric Ton

Price Breakdown:

CIF Veracruz-Mexico

Total Invoice Value : U.S. [redacted]

Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment. Importer point of contact is [redacted].

These commodities, technology, or software were exported from the United States in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited.

[redacted] is an equal opportunity employer, and this contract is subject to the rules and regulations imposed upon contractors and subcontractors pursuant to 41 C.F.R. Chapter 60. Unless this contract is exempt, there is incorporated herein by reference: 41 C.F.R. Section 60-1.4; 41 C.F.R. Section 60-250.4; and 41 C.F.R. Section 60-741.4."

SUBMISSIONS FROM ORGANIZATIONS

GLOBAL INDUSTRY COALITION (GIC) [30 JUNE 2004]
[SUBMISSION: ENGLISH]

In response to the request of the Exceutive Secretary to relevant international organizations to provide views and information on Article 18.2(a) of the Cartagena Protocol on Biosafety pursuant to Decision BS 1/6 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, the Global Industry Coalition[1] is pleased to address this request below.

The Executive Secretary specifically requested relevant international organizations to provide the following:

a) Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18;

b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2(a) of Article 18, including specification of the identity of the living modified organisms (LMOs) that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modification inserted and traits or genes changed); threshold levels in the case of co-mingling of LMOs with non-LMOs; and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification;

c) Information on experience with the use of existing unique identification systems under the Protocol, such as the Unique Identifier for Transgenic Plants of the Organization for Economic Co-operation and Development.

In order to avoid duplicative submissions, the GIC wishes to respond to the Executive Secretary's request by expressing agreement with the submission from the International Grain Trade Coalition (IGTC) on the specific areas listed above.

To avoid disruptions in international trade, the IGTC encouraged major exporters to use Article 24 of the Protocol to bring greater clarity to documentation requirements for LMOs destined for food, feed and processing (LMO-FFPs). Article 24 enables Parties to enter into arrangements with non-Parties on the transboundary movement of LMOs provided that the arrangements are consistent with the Protocol. With the signing of such an arrangement – the Trilateral Arrangement between Mexico, Canada and the U.S. – the IGTC issued a Notice to Trade for the international grain trade. This notice clarified the documentation requirements contained in the first sentence of Article 18.2(a) for any LMO-FFP shipments from Canada and the United States to Mexico made in advance of further implementation discussions by the Parties on the documentation requirements of this Article.

The GIC believes this Trilateral Arrangement provides a clear framework for implementation of the provisions of Article 18.2(a) of the Protocol since these implementation discussions are not yet complete. Additionally, the agreement is valuable in defining terms consistent with the Protocol for shipments between Parties and non-Parties. As the IGTC noted, no further disruptions to trade with Mexico have occurred since the Trilateral Agreement was put in place.

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[1] The Global Industry Coalition (GIC) represents over 2,300 firms from more than 130 countries worldwide. Its membership includes companies and trade associations from a variety of industrial sectors including plant and animal agriculture, food production, human and animal health care, and the environment.

Additional Input

The GIC supports the development of the OECD unique identifier system for transgenic plants and believes this system may be appropriate to use in some instances with regard to the Protocol. However, the use of a unique identifier should not ba a mandatory requirement under Article 18.2(a). The GIC agrees with the IGTC that a common unique identifier system may facilitate Parties' accesss to the most precise description of an LMO on the Biosafety Clearing-House (BCH).

A continuing concern of the GIC is the difficulty Parties are facing in meeting their obligations to implement the Protocol with regard to shipmnets of LMO-FFPs due to the lack of clear information from other Parties and non-Parties. One hundred countries have joined the Protocol to date, thus obligating themselves to follow its provisions, either directly or through Protocol-consistent domestic legislation. Non-Parties (and their technology providers or users) do not have direct obligations to comply with the Protocol itself, but must follow domestic legislation in the country in which they are based and to which they are shipping LMO-FFPs.

There are two basic provisions that Parties must follow related to LMO-FFP shipments:

- Parties must provide information to the BCH concerning: domestic regulations, LMOs that have been approved for domestic use, contact points, and other relevant information (Article 20); and
- Exporting Parties must take measures to require that Protocol-consistent shipping documentation accompanies transboundary movement of LMO-FFPs.

The BCH was established to provide access to information made available by the Parties relevant to the implementation of the Protocol and, where possible, to other international biosafety information exchange mechanisms (Article 20(2)). While the BCH is fully operational, the lack of information posted limits its utility. Parties have specific obligations regarding provision of information and shipment of LMO-FFPs. Few Parties, however, have posted the necessary information on the BCH that outlines how they intend to implement these provisions of the Protocol, or have otherwise clarified the applicable processes for LMO-FFP imports. Some countries, both Parties and non-Parties, have posted information regarding approvals for domestic use or import approvals, but only the EU, Switzerland and Norway have specifically indicated that their domestic regulations, including shipping regulations, apply to imports, including those of LMO-FFPs. Potential trade delays would be avoided by provision of specific requirements on shipping documentation by Parties. The GIC encourages the Secretariat to work with Parties to take immediate actions to post clarifying information consistent with the recommendations of the open-ended technical expert group on Article 18.2(a) to reduce any additional confusion and delays in shipments of LMO-FFPs that may otherwise occur. We suggest that specific information for shipping documentation under Article 18.2(a) follows the recommendations of the IGTC as found in the Trilateral agreement and outlined in their Notice to Trade.

The GIC hopes the information provided above will serve useful during the open-ended technical expert group on Article 18.2(a) to be held in Montreal in March 2005. We appreciate the opportunity for continued dialogue with the Parties, other Governments and relevant international organizations on this important issue.

INTERNATIONAL GRAIN TRADE COALITION (IGTC) [30 JUNE 2004]
[SUBMISSION: ENGLISH]

Background

The International Grain Trade Coalition (see Annex I) is pleased to provide views and information relevant to paragraph 2(a) of Article 18 of the Cartagena Protocol on Biosafety as requested by Decision BS-1/6 of the first Meeting of the Conference of the Parties serving as the Meeting of the Parties (COP-MOP-1).

The International Grain Trade Coalition (IGTC) was formed in June 2001 to encourage the adoption of international regulation to enable the global grain industry to remain effective in providing, through responsible and efficient international trade, a critical portion of the world's food and feed. The Coalition today has 17 trade organizations in 10 countries that in turn represent more than 2500 members in more than 80 countries that are involved in importing, exporting or food, feed and industrial processing.

On average, more than 300 million tonnes of grains, oilseeds, pulses and special crops are traded each year across international boundaries. A reliable and expanding volume of international trade in these crops is critical to maintaining and improving global food security. The current focus of the work of the IGTC is biosafety regulations as they impact international commerce in agricultural commodities. The IGTC recognizes the objective of the Cartagena Protocol on Biosafety (BSP) to introduce regulatory control over the transboundary movement of products of modem biotechnology that may have an adverse effect on the conservation and use of biological diversity. However, the IGTC has serious concerns on how the Protocol may impact the capability and cost of moving globally the large volumes of living modified organisms (LMOs) and non-LMOs required to meet the world's demands each year for food, feed and processing.

This submission focuses on the information requested in the letter to the IGTC on 13 April 2004 from Hamdallah Zedan, Executive Secretary of the Convention on Biological Diversity, namely:

(a) Information on experience, if any, in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18;

(b) Views regarding the detailed requirements referred to in the second sentence of paragraph 2(a) of Article 18, including specification of the identity of the living modified organisms (LMO-FFPs) that are intended for direct use as food, or feed, or for processing (whether the extent of the information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of commingling of LMO-FFPs with non-LMOs; and the possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification;

(c) Information on experience with the use of existing unique identification systems under the Protocol, such as the unique identifier for Transgenic Plants of the Organization for Economic Co-operation and Development."

The first sentence of Article 18 2 (a)

The first sentence of Article 18 2 (a) states that each Party (government) shall take measures to require that documentation accompanying:

" Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information."

The first sentence is general in nature and unfortunately leaves many documentation issues unresolved, resulting in some confusion and stoppages in LMO-FFP shipments since the Protocol entered into force on 11 September 2003.

Mexico / United States / Canada Trilateral Arrangement

To avoid disruptions in international trade, the IGTC has encouraged the governments of major exporters to use Article 24 of the Protocol to bring greater clarity to documentation requirements for grain destined for food, feed and processing through mechanisms available under Article 24. Article 24 enables Parties to enter into arrangements with non-Parties on the transboundary movement of LMO-FFPs provided that the arrangements are consistent with the Protocol.

The governments of Mexico, United States and Canada used the provisions contained in Article 24 to enter into a Trilateral Arrangement (see Annex II) to clarify the documentation requirements contained in the first sentence of Article 18.2(a). Following the signing of the Trilateral Arrangement, the IGTC issued Notice to Trade Number 2, informing the international grain trade of the documentation requirements for LMO-FFP shipments from Canada and the United States to Mexico.

Experience in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18;

The Trilateral Arrangement clarifies to industry how the documentation requirements contained in Article 18.2(a) should be implemented in LMO-FFP shipments to Mexico. What has been the experience?

1. Industry implemented the terms of the arrangement on its own initiative.

o Mexico became the first Party to comply with the documentation provisions of the Cartagena Protocol on Biosafety.

o As per the obligations set out in Article 18.2(a), LMO-FFP shipments entering the country carry the "may contain" documentation requirements.

o No disruptions in trade have occured in Mexican shipments since the Arrangement came into effect,

o The Protocol's first sentence requirements of Article 18.2(a) have been implemented in Mexican shipments in a manner to minimize costs.

2. Industry inserted the "may contain" information on the invoice.

o By placing the "may contain" statement on the same document, import officials do not have to search through all shipping documents to look for possible LMO-FFP documentation.
o By using the invoice that accompanies every shipment rather than using a stand-alone document, the import official knows immediately whether or not the shipment is an LMO-FFP shipment and not simply the case of a missing document.
o By using the invoice to carry the documentation requirements, the importer may advise the import official in advance of the arrival of the vessel whether or not the shipment is an LMO-FFP shipment as the invoice is sent by courier to the buyer immediately following loading and therefore arrives before the vessel or train.
o No unnecessary delays occur within the banking chain because the "may contain" clause is inserted on the invoice.

3. As per the obligations contained in Article 18.2(a), industry inserts on the invoice the following "may contain" language.

"Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

o The "may contain" language is as agreed upon at the Meeting of Technical Experts on the Requirements of Paragraph 2 (a) Article 18 which took place in Montreal, Canada from 18 to 20 March 2002 (UNEP/CBD/ICCP/3/7/Add. 1).
o The "may contain" language is the same on all LMO-FFP shipments entering Mexico.

4. Industry complies with the "contact point" requirement under Article 18.2 (a) by naming the last exporter prior to transboundary movement and the first importer after transboundary movement identified on the invoice as the contact points for further information.

o If required, the import official can easily contact the importer, taking advantage of the fact that the importer is in the same time zone and speaks the same language.
o The importer knows the terms of the contract and therefore is the most knowledgeable on what is contained in the shipment.
o When further information is required, the importer knows how to contact the exporter who can provide the information or, if more technical information is needed, knows how to obtain the information from the Competent National Authority (s) named by the country of export.

5. Industry knows when to use the documentation, for example, canola shipments from Canada to Mexico carry the "may contain" documentation. The "may contain" documentation is used for all transboundary movements into Mexico of LMO-FFP commodities intended for food or feed or for processing where the LMO-FFP of that commodity species covered under the scope of the Protocol is authorized in or sold from a country of export, except for those shipments for which:

(i) The exporting country does not have in commerce any LMO-FFP of that species;

o In some instances governments approve an event but the event is never commercialized and therefore will never appear in transboundary shipments. Confusion is avoided because these shipments do not have to carry the LMO-FFP documentation.

(ii) The exporter and importer have contractually defined a "non-LMO-FFP shipment;" provided, that such shipment achieves a minimum of 95% non-LMO-FFP content, and that such definition does not conflict with regulations of the importing country.

o In some instances importers purchase non-LMO-FFP shipments in which there is production of that LMO-FFP. These contracts have a purity level agreed to by buyer and seller. Once again, confusion is avoided in Mexican shipments, as these shipments do not carry the LMO-FFP documentation as long as they do not exceed the minimum 5% threshold mandated by the Trilateral Arrangement.

(iii) And finally, the industry knows that the unintentional presence of LMOs in a non-LMO-FFP shipment is not a trigger for the "may contain" documentation.

o Trace quantities of LMOs may appear in shipments of all commodities through unintentional commingling of LMO material with non-LMO material during the seed preparation, production, storage, handling and transportation of commodities. Therefore, if adventitious presence of LMOs in non-LMO-FFP shipments is a trigger for the "may contain" documentation, all shipments to Mexico would have had to carry the documentation and Mexican officials would not have been able to distinguish non-LMO-FFP shipments with possible trace LMO material from LMO-FFP shipments.

Preliminary conclusions on Mexico / United States / Canada Trilateral Arrangement Documentation Requirements

The clarification of the documentation requirements of the first sentence of Article 18.2(a) through the Trilateral Arrangement facilitated Mexico's capability to secure its grain import requirements at no additional cost and therefore the country is able to maintain its low cost food policy for its lower income population while also meeting the obligations of the Biosafety Protocol.

Case Study on Implementation of the First Sentence of Article 18.2(a)

'The IGTC is working with the governments of Mexico, United States and Canada to develop a case study to document how the Trilateral Arrangement triggers a process to protect Mexico's biodiversity without unnecessarily disrupting intemational trade of products for food, feed and processing.

The study will identify the total tonnes of grains for food, feed or processing shipped into Mexico during the period under review; the actions by exporters to insert the "may contain" language on the invoice; the tonnage of LMO-FFP shipments carrying the "may contain" documentation; the actions by the importer to provide the information to Mexican import authorities; the actions by Mexican import authorities to seek additional information from the importer, or the exporter, or the Biosafety Clearing House; the actions by the Mexican importers to ensure the LMO-FFP shipments were used for food, feed or for processing and that the shipment was not intentionally introduced into the environment; and the actions by the Mexican authorities to ensure compliance by Mexican industry. The study will also identify costs incurred by all parties.

The information from the case study will be made available to the Biosafety Secretariat for distribution to delegates attending the Expert Committee Meeting on Article 18.2(a) and to COP/MOP-2.

Second sentence of Article 18.2(a)

The Executive Secretary also asked for comments concerning "the detailed requirements referred to in the second sentence of paragraph 2(a) of Article 18, including specification of the identity of the living modified organisms (LMO-FFPs) that are intended for direct use as food, or feed, or for processing (whether the extent of the information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of commingling of LMO-FFPs with non-LMO-FFPs; and the possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification."

The second sentence of Article 18 2 (a) states:

"The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;"

The Convention of Parties serving as the first Meeting of Parties (COP/MOP-1) met in Kuala Lumpur 23-27 February 2004 and decided to urge governments to require that documentation accompanying living modified organism (LMO-FFP) shipments for food, feed or for processing includes: "(i) the common, scientific and, where available, commercial names, and (ii) the transformation event code of the living modified organisms or, where available, as a key to accessing information in the Biosafety Clearing House, its unique identifier code." What will be the impact of implementing this requirement in international trade?

Quite simply, the world's grain industry is placed in a position of meeting unreasonable expectations related to the identification of LMO-FFP events in shipments. Factors beyond the control of the grain shipper severely limit and may prevent the grain industry from meeting regulatory requirements and the expectations of some to determine with a high degree of accuracy the specific events in each shipment. That is why the IGTC has advocated the "may contain" provision. The following observations further explain the dilemma:

- No sampling technique, other than the destructive testing of each individual seed in a shipment can provide 100% confidence. The purity of planting seeds is never 100% resulting, through propagation, in variability in genetic content commodity seeds. Commodity seeds are necessarily mixed throughout harvest, conditioning, storage and transportation systems. Once an event is approved for commercial production by the country of export, it is only a matter of time before that event may be in any bulk shipment - in minute, adventitious amounts.

- There is no internationally acceptable LMO-FFP sampling and testing system that is compatible with high-speed modern bulk export grain terminals. If industry tried to identify specific events,

test results could vary significantly between exporter and importer. Who carries the liability when tests are so variable?

- And for some commodities, such as corn and canola with numerous traits approved and in commercial production, there is no single test available to identify all of the specific traits that might be in bulk shipments. How can industry or government ensure compliance when no satisfactory tests are available to identify specific traits in a multi-trait shipment?
- To complicate matters further, there is no definition of an LMO-FFP shipment in the COP/MOP-l decision document. How does industry know when documentation is required? Is it when trace amounts of an LMO are present as adventitious materials? Or is it when the contract says that the shipment contains a commodity that has commercial LMO production in the country of export? Are there any exceptions? If so, what are they? These issues must be resolved.

The IGTC believes that the documentation accompanying LMO-FFP shipments should be viewed in the context of the information contained in the Biosafety Clearing House (BCH). The "may contain" statement on the invoice is an early notification to import officials that a shipment is enroute that may contain LMO-FFP material and allows the importing government to take whatever action it deems necessary to protect its biodiversity. It is likely that in most cases no action will be taken; however, importing countries may seek more information from the importer, or from the exporter, or from the BCH.

It is the responsibility of the country of export, working with the Secretariat, to ensure that the information contained on the BCH is:

- Easy to access
- Easy to understand
- Current
- Provides detailed information including the taxonomic name, the gene modifications inserted and traits or genes changed, and if available, the unique identifier
- Provides detailed risk assessment analysis evaluating potential adverse effects of LMOs on biological diversity

The country of export must also indicate in the BCH whether or not the event has been commericalized and therefore likely to be present in bulk shipments. The information contained on the BCH together with the invoice "may contain" information should provide the importing country with sufficient information to take the necessary steps to protect its biodiversity and meet the documentation requirements contained in Article 18.2 (a).

Thresholds

The IGTC believes that thresholds of LMO material in non-LMO shipments for food, feed or for processing are necessary to determine when the "may contain" documentation is required. The IGTC recommends a 95% punty level be exempt from documentation requirements as a temporary measure until specific thresholds are developed based on science based risk analysis.

The IGTC encourages the CODEX Alimentarius Commission and the International Plant Protection Committee to fast track the development of science based risk management thresholds for LMO material in non-LMO products.

Article 17

The Executive Secretary also asked that the IGTC comment on Article 17, "Unintentional Transboundary Movements and Emergency Measures,"

Article 17 reads in part as follows:

"Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

The IGTC believes that adventitious presence of LMOs in non-LMO shipments does not constitute an unintentional transboundary movement covered by Article 17.

Unique Identifier Systems

The IGTC supports the development of an internationally recognized and applicable unique identifier system for commercially available products. Today, often different names or numbers refers to the same event by different departments within the same government, in addition to the differences among governments. A common unique identifier system would remove confusion and facilitate improved understanding regarding commercial products. However the unique identifier system should be used within the BCH and not on shipping documentation.

The IGTC has contacted the International Food and Agricultural Trade Policy Council (IPQ about conducting a study to determine the potential economic impact of identifying specific events upon the international grain trade. However, studies in several countries into the impact of changing bulk handling practices to provide for increased segregation of LMO and non-LMO commodities for food, feed or processing significantly increases the cost of storage, handling and transport services. Studies have estimated the increase in costs to be in the order of 10-25%.

Conclusions

The Trilateral Arrangement provides important guidance on how to implement Article 18.2 (a) to facilitate trade. The Mexican Case Study will illustrate how the Trilateral Arrangement can also be used to trigger a process to protect a country's biodiversity.

Following COP/MOP- 1, the IGTC issued Notice to Trade Number 4 (see Annex III) to recommend to the international grain export industry that the "may contain" statement should be placed on all LMO shipments to all countries that are Parties to the Protocol. However, there has not been sufficient time to determine the results.

Annex 1:
INTERNATIONAL GRAIN TRADE COALITION MEMBERS AND CONTACT POINTS

The Grain and Feed Trade Association (GAFTA): GAFTA is the only worldwide trade association representing the interests of members, who trade in grains, feeding stuffs, pulses and rice internationally, with over 800 members in 80 countries, **Contact Point:** Pamela Kirby Johnson, Director General, GAFTA House, 6 Chapel Place, Rivington Street, London, EC2A 3SH, United Kingdom, Tel: 44 20 7814 9666, Fax: 44 20 7814 8383 Email: PamelaKirbyJohnson@gafta.com

The North American Export Grain Association (NAEGA): NAEGA is comprised of grain and oilseed exporters and interested parties whose purpose is to promote and sustain the development of commercial export grain and oilseed trade from the United States. NAEGA members include 35 private and publicly owned companies and cooperatives domiciled in the United States and Canada. **Contact Point:** Gary C. Martin, President and CEO, North American Export Grain Association, Incorporated, Suite 1003, 1250 Eye Street NW, Washington, D.C. 20005, Tel: 202 682 4030, Fax: 202 682 4033, Email: gcmartin@naega.org

COCERAL: COCERAL is the representation of the European trade in cereals, feedstuffs, oilseeds, olive oil, vegetable oil and agrosupply. It comprises the trade organizations in 15 EU member states, that for their part represent collectors, distributors, exporters, importers and storekeepers of the above-mentioned commodities. Furthermore COCERAL has associated members in Hungary, Poland and Switzerland. **Contact Point:** Klaus Schumacher, Chairman, or Chantal Fauth, Secretary General, COCERAL, 18 Square de Meeus, B 1050 Brussels, Belgium, Tel 02 502 08 08, Fax 02 502 60 30, Email: secretariat @coceral.com

Canada Grains Council (CGC): CGC has a membership of about 30 organizations involved in Canada's grains, oilseeds, pulses and special crops industry including producers, handlers, transporters, processors, exporters, banks and provincial and federal governments and their agencies. **Contact Point:** Dale Adolphe, Chairman Biosafety Committee, or Patty Rosher, Member, Biosafety Committee or Dennis Stephens, Consultant, Canada Grains Council, 1215-220 Portage Avenue, Winnipeg, MB, R3C OA5, Canada Tel 204 925 2133, Fax 204 925 2132, Email: dstephens@canadagrainscouncil.ca

AWB Limited (Australian Wheat Board): AWB Limited is Australia's major national grain marketing organization and is one of the world's largest wheat management and marketing companies. It is involved in the management and marketing of wheat (for which it is the nation's exclusive bulk exporter) as well as other grains including barley, sorghum, oilseeds and pulses. **Contact Point:** James Molan or Mathew Foran; Ceres House, 528 Lonsdale Street, Melbourne 3000,Victoria, Australia Tel 613 9209 2555; mobile 61407 920 911; email jmolan@awb.com.au. or mforan@awb.com.au

National Grain and Feed Association (NGFA): NGFA consists of 1,000 grain, feed, processing and grain related companies that operate about 5,000 facilities that store, handle, merchandise, mill, process and export more than two-thirds of all US grains and oilseeds. About 70% of NGFA member firms are small businesses - country elevators and feed mills. Also affiliated with NGFA are 36 state and regional grain and feed associations. **Contact Point:** Mr. Tom O'Connor, Director of Technical Services, National Grain and Feed Association, Suite 1003, 1250 Eye Street NW, Washington, D.C. 20005. Email toconnor@ngfa.org

Soybean Processors Association of India (SOPA): SOPA is an all India based association having a membership of 600 members representing processing industries, exporters, buyers, brokers, surveyors, analysts as well as farmers. The Association members are actively involved in trading soybean meal for food and feed purposes. **Contact Point:** Mr. D. R. Kalra, Executive Director, Soybean Processors Association of India, Scheme No. 53, Bear Malviya Nagar, A. B. Road, Indore 452 008, India, Email sopain@bom4.vsnl.net.in

ANIAME: ANIAME is the Association of Oilseed (including soya, canola and sunseeds) Processors in Mexico. **Contact Point:** Lic Amadeo Ibarra, Director General, ANIAME, Praga 39 Piso 3, Col. Juarez, C. P. 06600, Mexico, D.F., Mexico, Email aibarra@aniame.com

Hungarian Grain and Feed Association: The Hungarian Grain and Feed Association represents 80 -90% of the companies involved in Hungary's milling, grain-export, soymeal-import and feed milling industry. **Contact Point:** Mr. George Makay, General Secretary, Hungarian Grain and Feed Trade Association, Alkotmany U. 16.11.9, H- 1054 Budapest, Hungary, Email gabonaszov@mail.datanet.hu

The Solvent Extractors' Association of India: The Solvent Extractors' Association of India was formed in 1963 to help and foster the development and growth of India's solvent extraction industry. At present the Association has about 900 members including about 550 solvent extraction plants having a combined oilcake/oilseed processing capacity of about 30 million tonnes. **Contact Point:** Mr. B.V. Mehta, Executive Director, 142 Jolly Maker Chambers No 2, 14 1h Floor, 225, Nariman Point, Mumbai-400 021 hidia, Email solvent@vsnl.com

National Corn Growers Association (NCGA): NCGA is a coalition of 27 affiliated state organizations and represents the interests of 350,000 corn producers in the United States. **Contact Point:** Mr. Fred Yoder, Chairman, National Corn Growers Association, Email seedman@netwalk.com or Hayden Milberg, e-mail: milberg@dc.ncga.com

APPAMEX: The Mexican Association of Providers of Agricultural Products represents organizations involved in the trade of imported and exported agricultural commodities in Mexico. **Contact Point:** Ricardo Calderon, Director, Durango 245 Desp. 203, Col. Roma, 06700 Mexico D.F, phone (5255) 5533-4339, fax (5255) 5525-2776 Email **appamex@prodigy.net.rnx**

US Wheat Associates: US Wheat Associates is the market development arm of the US wheat industry. **Contact Point:** Nelson Denlinger, US Wheat Associates, Suite 801, 1620 1 Street, N.W., Washington, D.C. 20006-4005, Email: ndenlinger@uswheat.org

Centro de Exportadores de Cereales (Chamber of Grain Exporters of the Argentinean Republic: The Chamber was formed in 1944 and includes the 12 largest grain exporters, marketing approximately 30 million tonnes per year. **Contact Point:** Ciro Echesortu, President, or Gabriel Gilges, General Manager, or Alberto Rodriguez, Bouchard 454 7th floor, Cl 106ABF, Buenos Aires, Argentina, phone 54 11 4311 1697, fax: 54 114311 7767, Email: Cerex@datamarkets.com.ar

Wheat Export Trade Education Committee: WETEC is responsible for carrying out activities that advance and help formulate the trade policies of the U.S. wheat industry. **Contact Point:** Barbara Spangler, Executive Director, 415 Second Street, N.E., Suite 300, Washington, D.C. 20002. Tel 202-547-2004, Fax 202-546-2638, e-mall: Spangler@USWheat.org.

US Grains Council: The U.S. Grains Council builds global markets and serves international customers for U.S. grains through a unique partnership of U.S. producers, agribusiness and the public sector. **Contact Point:** David McGuire, Director of Biotechnology, 1400 K Street NW, Suite 1200 Washington, DC 20005, phone: (202) 789-0789, fax: (202) 326-0660, Email: dmcguire@grains.org; Web site: http://www.grains.org

Russian Grain Union: Contact Point: Arkady Zlochevsky, President: 107139, Moscow, Orlikov Per, 1/11, Office 576, 821: Tel: (095) 207-8256, 207-8285, 207-8345, 2075279 Tel/Fax: (095) 207-8379, 207-5344; E-mail: rgumsk@dol.ru

Annex II

IGTC NOTICE TO TRADE NUMBER 2

Notice to Trade # 2

The Governments of the United States, Mexico and Canada have entered into a Trilateral Arrangement to define documentation requirements under Article 18.2(a) of the Cartagena Protocol on Biosafety for shipments of LMOs for food, feed or for processing.

Article 24 of the Protocol enables bilateral or regional arrangements among Parties and Non-Parties. The arrangement (see below) is designed to fulfill the Protocol's objectives without unnecessarily disrupting international commodity trade. The document incorporates many of the recommendations of the International Grain Trade Coalition (IGTC) and confirms that adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation. It also exempts shipments from documentation requirements "when the exporter and importer have contractually defined a 'non LMO shipment;' provided, that such a shipment achieves a minimum of 95 per cent non-LMO content, and that such definition does not conflict with regulations of the importing country."

As of 24 November 2003, 75 countries have ratified the Protocol. Importers in countries that have ratified the Protocol should discuss with their respective governments the desirability of entering into similar agreements with the governments of major exporters. Some disruptions to international trade have occurred since the Protocol came into force on 11 September 2003 as NGOs picketed ships claiming that the shipments did not have the required documentation. Arrangements such as that by the United States / Mexico / Canada should minimize such disruptions as the shipments will have the required documentation under the Protocol as agreed to by the appropriate governments.

If any organization has questions concerning the arrangement please contact a member of the International Grain Trade Coalition listed on this Notice to Trade.

The text of the arrangement is as follows:

United States / Mexico / Canada Trilateral Arrangement

Documentation Requirements for Living Modified Organisms

for Food or Feed, or for Processing (LMO/FFP’s)

The purpose of this document is to articulate an understanding among the United States, Canada, and Mexico, hereinafter also referred to as the "Participants," with respect to the documentation requirements of the Cartagena Protocol on Biosafety (CPB) pertaining to living modified organisms intended for direct use as food or feed, or for processing (LMO/FFP's). Specifically, the objective of this arrangement is to clarify documentation requirements such that they fulfill the objectives of the CPB without unnecessarily disrupting commodity trade.

The United States and Canada are not Parties to the CPB at this time. However, Article 24 states that transhoundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objectives of the CPB, and that Parties and non-Parties may enter into arrangements, such as this, regarding such transboundary movements. This arrangement also meets the requirements in Article 14 of the CPB to accommodate the eventuality of either the United States or Canada becoming a Party to the CPB.

Article 18.2(a) of the CPB states:

"Each Party shall take measures to require that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information.

"The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol."

Article 18.2(a) of the CPB will be implemented as follows:

1. The "may contain" language, when included as per section 4 below, should appear on the commercial invoice as provided by the exporter. The importer is responsible for receiving the invoice and maintaining it after entry.

2. The "may contain" language, when included, should state:

"Cartagena Biosafety Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

3. The last exporter prior to the transboundary movement and the first importer after the transboundary movement are to be named on the invoice and are the contact points for further information.

4. Applicability:

a. The "may contain" documentation will be used for all transboundary movements of commodities intended for food or feed, or for processing, where an LMO of that commodity species is authorized1 in, or sold from, a country of export, except:

(i) Shipments for which the exporting country does not have in commerce any LMO of that species; or

(ii) When the exporter and importer have contractually defined a “non-LMO shipment;" provided, that such a shipment achieves a minimum of 95 percent non-LMO content, and that such definition does not conflict with regulations of the importing country.

b. Adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation.

Mexico (as a Party), Canada and the United States (currently as non-Parties) affirm that exporters and importers trading commodities with documentation according to these provisions have fulfilled both the objectives and the current requirements of Article 18.2(a) of the CPB.

The Participants hereby intend to maintain a continuous exchange of scientific information and to address issues on agricultural biotechnology that may arise among the three nations utilizing the expertise of scientific personnel. The Participants will elaborate on the subjects and mechanisms for information exchange.

This arrangement does not affect a Participant's decision on the import of LMO/FFPs under its domestic regulatory framework or according to a risk assessment, pursuant to Article 11 of the CPB.

Whenever in the judgment of a Participant issues of concern arise that would require further consultation on the interpretation or implementation of this document, including relevant decisions of the Meeting of Parties to the CPB, the Participants may jointly decide to make the necessary modifications and/or updates.

1/ Approved for unconfined release (Canada), deregulated (United States), or approved (Mexico), noting that the Biosafety Clearing-House is an important reference tool.

This document will have effect for a period of two years, starting at the date of its signature, It can remain in effect beyond two years with mutual consent of all Participants.

Participant Signatures:

SIGNED

Date: OCTOBER 29,2003

Victor Manuel Villalobos Ardinbula
Coordinator of International Affairs
Office of the Secretary
Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food of Mexico (SAGARPA)

SIGNED

Date: October 23, 2003

J.B. Penn
Under Secretary
Farm and Foreign Agricultural Services
U.S. Department of Agriculture

SIGNED

Date: OCTOBER 20,2003

Andrew Marsland
Assistant Deputy Minister
Market and Industry Services Branch
Agriculture and Agri-Food Canada

Annex III

IGTC NOTICE TO TRADE NUMBER 4

Notice to Trade # 4

Re: Documentation Requirements of the Cartagena Protocol on Biosafety

The following information addresses actions that impact the documentation requirments for the transboundary movement of living modified organisms (LMOs for food, feed or for processing that were taken at the recent meeting of countries that are Parties to the Cartagena Protocol on Biosafety, -- an international agreement on biodiversity.

The actions recommended below are based upon the best information known to date and the advice provided by the International Grain Trade Coalition (IGTC) to government on how to implement the Protocol to meet the needs of the world's food, feed and processing industry.

The following is not intended as legal advice or opinion. Entities impacted by the Biosafety Protocol (those that are engaged in the international movement of products that may contain living modified organisms derived from modern biotechnology) are strongly recommneded to contact their legal counsel and regulatory affairs representatives for further information in order to make necessary decisions oncerning the matters in this overview.

The Meeting of the Parties to the Cartagena Protocol on Biosafety recently confirmed that transboundary shipments of living modified organisms for food, feed or for processing must be accompanied by documentation stating that the shipment may contain LMOs for direct use as food, feed or for processing and that the shipment is not intended for intentional introduction into the environment.

Unfortunately no clear or single option emerged on how the documentation requirements of Article 18.2(a) should be managed or when the documentation should be used.

As of May 4, 2004, more than 90 countries have ratified the Protocol and therefore are obligated to follow the Protocol's requirements.

The International Grain Trade Coalition (IGTC) recommends that industry check the Biosafety Clearing House at http://bch.biodiv.org before exporting to determine whether or not the country of destination has ratified the Protocol and if so, whether or not the the country has adopted domestic regulations defining documentation requirements for LMO imports.

In order to avoid trade distruptions and promote consistency in the implementation of the Protocol in international commerce, the IGTC recommends the provisions of the Trilateral Arrangement negotiated by Mexico, United States and Canada be the basis for commerical transactions between exporters and importers in all LMO shipments for food, feed or for processing to all Parties, unless domestic regulations of the importing country demand otherwise.

The Trilateral Arrangement states that Article 18.2(a) of the CPB will be implemented as follows:

1. The "may contain" language, when included as per section 4 below, should appear on the commercial invoice as provided by the exporter. The importer is responsible for receiving the invoice and maintaining it after entry.

2. The "may contain" language, when included, should state:

"Cartagena Biosafety Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

3. The last exporter prior to the transboundary movement and the first importer after the transboundary movement are to be named on the invoice and are the contact points for further information.

4. Applicability:

a. The "may contain" documentation will be used for all transboundary movements of commodities intended for food or feed, or for processing, where an LMO of that commodity species is authorized1 in, or sold from, a country of export, except:

i. Shipments for which the exporting country does not have in commerce any LMO of that species; or

ii. When the exporter and importer have contractually defined a "non-LMO shipment;" provided, that such a shipment achieves a minimum of 95 percent non-LMO content, and that such definition does not conflict with regulations of the importing country.

b. Adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation.

This arrangement is designed to fulfill the Protocol's objectives without unnecessarily disrupting international commodity trade. The Trilateral Arrangement incorporates many of the recommendations of the IGTC, including the recommendation that adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation. It also exempts shipments from documentation requirements "when the exporter and importer have contractually defined a 'non-LMO shipment; provided, that such a shipment achieves a minimum of 95 per cent non-LMO content, and that such definition does not conflict with regulations of the importing country."

Importers in countries that have ratified the Protocol should discuss with their respective governments the desirability of entering into similar arrangements with the governments of major exporters. Some disruptions to international trade have occurred since the Protocol came into force on 11 September 2003 as NGOs picketed ships claiming that the shipments did not have the required documentation.

However, even without formal arrangements among governments, such disruptions may be minimized by following the procedures discussed above, as the Trilateral Arrangement is designed to meet the required documentation under the Protocol, unless the importing country's domestic regulations as outlined on the Biosafety Clearing House say otherwise.

If any organization has questions concerning these recommendations please contact a member of the International Grain Trade Coalition listed below:

International Grain Trade Coalition Members and Contact Points

The Grain and Feed Trade Association (GAFTA): GAFTA is the only worldwide trade association representing the interests of members, who trade in grains, feeding stuffs, pulses and rice internationally, with over 800 members in 80 countries. **Contact Point:** Pamela Kirby Johnson, Director General, GAFTA House, 6 Chapel Place, Rivington Street, London, EC2A 3SH, United Kingdom, Tel: 44 20 781.4 9666, Fax: 44 20 7814 8383 Email: PamelaKirbyJohnson@gafta.com

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1/ Approved for unconfined release (Canada), deregulated (United States), or approved (Mexico), noting that the Biosafety Clearing House is an important reference tool.

The North American Export Grain Association (NAEGA): NAEGA is comprised of gain and oilseed exporters and interested parties whose purpose is to promote and sustain the development of commercial export grain and oilseed trade from the United States. NAEGA members include 35 private and publicly owned companies and cooperatives domiciled in the United States and Canada, **Contact Point:** Gary C. Martin, President and CEO, North American Export Grain Association, Incorporated, Suite 1003, 12SO Eye Street NW, Washington, D.C. 20005, Tel: 202 682 4030, Fax: 202 682 4033, Email: gcmartin@naega.org

COCERAL: COCERAL is the representation of the European trade in cereals, feedstuffs, oilseeds, olive oil, vegetable oil and agrosupply. It comprises the trade organizations in 15 EU member states, that for their part represent collectors, distributors, exporters, importers and storekeepers of the above-mentioned commodities. Furthermore COCERAL has associated members in Hungary, Poland and Switzerland. **Contact Point:** Klaus Schumacher, Chairman, or Chantal Fauth, Secretary General, COCERAL, 18 Square de Meeus, B 1050 Brussels, Belgium, Tel 02 502 08 08, Fax 02 502 60 30, Email: secretariat@coceral.com

Canada Grains Council (CGC): CGC has a membership of about 30 organizations involved in Canada's grains, oilseeds, pulses and special crops industry including producers, handlers, transporters, processors, exporters, banks and provincial and federal governments and their agencies. **Contact Point:** Dale Adolphe, Chairman Blosafety Committee, or Patty Rosher, Member, Biosafety Committee or Dennis Stephens, Consultant, Canada Grains Council, 1215-220 Portage Avenue, Winnipeg, MB, R3C OA5, Canada Tel 204 925 2133, Fax 204 925 2132, Email: dstephens@canadagrainscouncil.ca

AWB Limited (Australian Wheat Board): AWB Limited is Australia's major national grain marketing organization and is one of the world's largest wheat management and marketing companies. It is involved in the management and marketing of wheat (for which it is the nation's exclusive bulk exporter) as well as other grains including barley, sorghum, oilseeds and pulses. **Contact Point:** James Molan or Mathew Foran; Ceres House, 528 Lonsdale Street, Melbourne 3000,Victoria, Australia Tel 613 9209 2555; mobile 61407 920 911; email jmolan@awb.com.au. or mforan@awb.com.au

National Grain and Feed Association (NGFA): NGFA consists of 1,000 grain, feed, processing and grain related companies that operate about 5,000 facilities that store, handle, merchandise, mill, process and export more than two-thirds of all US gains and oilseeds. About 70% of NGFA member firms are small businesses country elevators and feed mills. Also affiliated with NGFA are 36 state and regional grain and feed associations. **Contact Point:** Mr. Tom O'Connor, Director of Technical Services, National Grain and Feed Association, Suite 1003, 1250 Eye Street NW, Washington, D.C. 20005. Email toconnor@ngfa.org

Soybean Processors Association of India (SOPA): SOPA is an all India based association having a membership of 600 members representing processing industries, exporters, buyers, brokers, surveyors, analysts as well as farmers. The Association members are actively involved in trading soybean meal for food and feed purposes. **Contact Point:** Mr. D. R. Kalra, Executive Director, Soybean Processors Association of India, Scheme No. 53, Bear Malviya Nagar, A. B. Road, Indore 452 008, India, Email sopain@bom4.vsnl.net.in

ANIAME: ANIAME is the Association of Oilseed (including soya, canola and sunseeds) Processors in Mexico. **Contact Point:** Lic Amadeo lbarra, Director General, ANIAME, Praga 39 Piso 3, Col. Juarez, C. P. 06600, Mexico, D.F., Mexico, Email aibarra@aniame.com

Hungarian Grain and Feed Association: The Hungarian Grain and Feed Association represents 80 -90% of the companies involved in Hungary's milling, grain-export, soymeal-import and feed milling industry. **Contact Point:** Mr. George Makay, General Secretary, Hungarian Grain and Feed Trade Association, Alkotmany U. 16.11.9, H- 1054 Budapest, Hungary, Email gabonaszov@mail.datanet.hu

The Solvent Extractors' Association of India: The Solvent Extractors' Association of India was formed in 1963 to help and foster the development and growth of India's solvent extraction industry. At present the Association has about 900 members including about 550 solvent extraction plants having a combined oilcake/oilseed processing capacity of about 30 million tonnes. **Contact Point:** Mr. B.V. Mehta, Executive Director, 142 Jolly Maker Chambers No 2, 14'h Floor, 225, Nariman Point, Mumbai-400 021 India, Email solvent@vsnl.com

National Corn Growers Association (NCGA): NCGA is a coalition of 27 affiliated state organizations and represents the interests of 350,000 corn producers in the United States. **Contact Point:** Mr. Fred Yoder, Chairman, National Corn Growers Association, Email seedman@netwalk.com or Hayden Milberg, e-mail: milberg@dc.ncga.com

APPAMEX: The Mexican Association of Providers of Agricultural Products represents organizations involved in the trade of imported and exported agricultural commodities in Mexico. **Contact Point:** Ricardo Calderon, Director, Durango 245 Desp. 203, Col. Roma, 06700 Mexico D.F, phone (5255) 5533-4339, fax (5255) 5525-2776 Email **appamex@prodigy.net.mx**

US Wheat Associates: US Wheat Associates is the market development arm of the US wheat industry. **Contact Point:** Nelson Denlinger, US Wheat Associates, Suite 801, 1620 1 Street, N.W., Washington, D.C. 20006-4005, Email: ndenlinger@uswheat.org

Centro de Exportadores de Cereales (Chamber of Grain Exporters of the Argentinean Republic: The Chamber was formed in 1944 and includes the 12 largest grain exporters, marketing approximately 30 million tonnes per year. **Contact Point:** Ciro Echesortu, President, or Gabriel Gilges, General Manager, or Alberto Rodriguez, Bouchard 454 7th floor, C1 106ABF, Buenos Aires, Argentina, phone 54 114311 1697, fax: 54 114311 7767, Email: Cerex@datamarkets.com.ar

Wheat Export Trade Education Committee: WETEC is responsible for carrying out activities that advance and help formulate the trade policies of the U.S. wheat industry. **Contact Point:** Barbara Spangler, Executive Director, 415 Second Street, N.E., Suite 300, Washington, D.C. 20002. Tel 202-547-2004, Fax 202-546-2638, e-mail: Spangler@USWheat.org.

US Grains Council: The U.S. Grains Council builds global markets and serves international customers for U.S. grains through a unique partnership of U.S. producers, agribusiness and the public sector. **Contact Point:** David McGuire, Director of Biotechnology, 1400 K Street NW, Suite 1200 Washington, DC 20005, phone: (202) 789-0789, fax: (202) 326-0660, Email: dmcguire@grains.org; Web site: http://www.grains.org

Russian Grain Union: Contact Point: Arkady Zlochevsky, President: 107139, Moscow, Orlikov Per, 1/11, Office 576, 821: Tel: (095) 207-8256, 207-8285, 2078345, 207-5279 Tel/Fax: (095) 207-8379, 207-5344; E-mail: rgumsk@dol.ru

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